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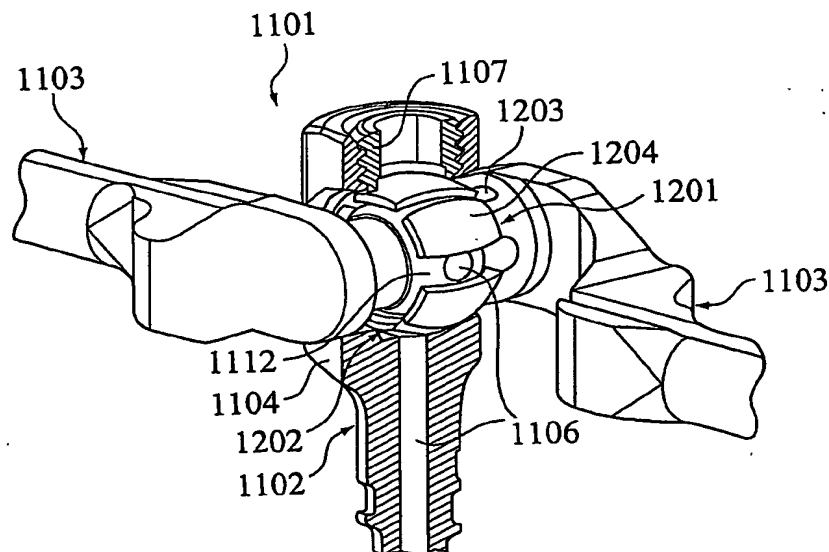
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[Continued on next page]

(54) Title: **SCREW ASSEMBLY**



(57) Abstract: A medical device and methods of use thereof are provided for supporting a structure (e.g., bone). A screw assembly (1, 101, 1101) is provided that can include a base (3, 102, 1102), one or more arms, and an interconnection means (4, 105) for coupling the base to the one or more arms. The interconnection means can allow the arm to be positionable in a first position that is parallel to a long axis of the base and positionable in a second position that is perpendicular to the long axis of the base. The base can be configured for attachment to a structure and the one or more arms configured for attachment to one or more support structures. A support structure (10) can be provided that includes an aperture (11) having locking means (9, 1107), which can be configured as an open-ended saddle for attachment to a medical device (e.g., a screw assembly) after installation in a patient.

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## **SCREW ASSEMBLY**

### **TECHNICAL FIELD**

**[0001]** This invention relates to medical devices.

### **BACKGROUND**

**[0002]** The use of spinal stabilization/fixation devices to align or position specific vertebra or a region of the spine is well established. Typically such devices utilize a spinal fixation element, comprised of a relatively rigid member such as a plate, board or rod that is used as a coupler between adjacent vertebrae. Such a spinal fixation element can effect a rigid positioning of adjacent vertebrae when attached (e.g. to the pedicle portion of the vertebra) using bone anchorage screws (e.g. pedicle screws). Once the coupled vertebrae are spatially fixed in position, procedures can be performed, healing can proceed or spinal fusion may take place.

**[0003]** Spinal fixation elements may be introduced posteriorly to stabilize the various vertebrae of the spine, for example, in conjunction with a kyphoplasty procedure wherein a void or cavity is made inside a vertebral body followed by filling with a bone substitute to form an "internal cast." Some conventional devices for this purpose are designed to be attached directly to the posterior of the spine, but the generally invasive nature of a conventional posterior approach used to implant these devices poses drawbacks. One minimally invasive solution to the problem of the posterior approach involves making a longitudinal separation of the sacrospinalis group between the multifidus and longissimus utilizing the natural cleavage plane between these two muscles rather than detaching the paraspinal muscles from the posterior spinal elements. Problems stemming from the prior art solutions include a high degree of invasiveness resulting in muscle disruption and blood loss. The loss of the paraspinal muscle attachment sites, formation of scar tissue, and loss of muscle function may compromise the patient's final outcome. Additionally, the prior art solutions are time consuming and are difficult to remove.

## SUMMARY

[0004] In general, in one aspect, the invention provides a medical device for supporting a structure comprising a screw assembly. The screw assembly includes a base, an arm, and an interconnection means for coupling the base to the arm. The interconnection means allows the arm to be positionable in a first position that is parallel to a long axis of the base and positionable in a second position that is perpendicular to the long axis of the base. The base is configured for attachment to a structure in a patient and the arm configured for attachment to a support structure. In one implementation, the structure attached to is bone.

[0005] The device can include a support structure and the screw assembly can be attached to the support structure by the arm. Alternatively, two screw assemblies can be attached to the support structure.

[0006] The screw assembly can be comprised of a material selected from the group consisting of titanium, stainless steel, carbon fiber, shape memory metal, a biocompatible material and a reabsorbable material and a composite or combination thereof. Alternatively, the screw assembly can be comprised of a continuous piece of shape memory metal. In one implementation the interconnection means is comprised of shape memory metal. In another implementation, the screw assembly, including the interconnection means is comprised of a piece of metal suited for bending.

[0007] The screw assembly can be of varying lengths, including an overall length in the range substantially between 0.1 and 100 centimeters. In one implementation, the overall length is in the range substantially between 50 and 600 millimeters. In another implementation, the screw assembly has an overall length sized for subcutaneous support of the spine. In yet another implementation, the screw assembly has an overall length sized for subcutaneous support of the posterior of a spine.

[0008] The arm of the screw assembly can be comprised of a body, a base yoke and a connector end. The body of the arm can be any of a number of shapes including rod shaped.

[0009] The base of the screw assembly can be comprised of a base head and an anchor. The anchor can be selected from the group consisting of a screw, staple, hook or nail. In one implementation the anchor is a screw configured for bone anchoring. In

another implementation, the anchor is a screw configured for insertion into the pedicle of a vertebrae.

[0010] The interconnection means of the screw assembly can be of any of a number of configurations. In one implementation, the interconnection means includes a press-fit cross pin. In another implementation the interconnection means is comprised of an open saddle head and coupling cross piece. The interconnection means can also include a setscrew, wherein the setscrew holds the arm and the base together as a single unit. Additionally, the setscrew can be tightened within the interconnection means to effect locking of the arm in a position that is substantially perpendicular to the long axis of the base. In another implementation, the locking means can also include a cam that can function analogously to the setscrew.

[0011] In one implementation, the device can be comprised of one screw assembly and a support structure, wherein the support structure includes a top surface, a bottom surface, an aperture and two receivers. In this implementation, the aperture can pass from the top surface through to the bottom surface of the support structure, wherein an anchor is disposed within the central aperture in an orientation substantially perpendicular to the top surface of the support structure.

[0012] The support structure of the device can be comprised of a top surface, a bottom surface and two receivers. Each receiver can include an open-ended saddle type receiver configured for attachment of one or more medical devices. Additionally, each receiver can include a locking means. The locking means can be a setscrew or cam. The locking means can be oriented within the plane of the top surface such that access to the locking means is from the top surface. The support structure can be configured to receive the medical devices and lock the medical devices to the support structure after the support structure has been installed.

[0013] The support structure can be comprised of a material selected from the group consisting of titanium, stainless steel, carbon fiber, a biocompatible material, a reabsorbable material and a composite or combination thereof. Additionally, the support structure can include a central aperture passing from the top surface through to the bottom surface of the support structure. An anchor can be disposed within the central aperture in an orientation substantially perpendicular to the top surface of the support structure.

Alternatively, the support structure can include a central hinged claw having a threaded hinge-engagement member and nut disposed on the top surface. In use, tightening the nut onto the threaded hinge-engagement member causes a pivoting about the hinge to effect closing of the claw.

[0014] The device can be comprised of two screw assemblies and a support structure, wherein each screw assembly includes a base, an arm, and an interconnection means for coupling the base to the arm. The interconnection means allows the arm to be positionable in a first position that is parallel to a long axis of the base and positionable in a second position that is perpendicular to the long axis of the base. In this implementation, the base can be configured for attachment to a structure in a patient and the arm configured for attachment to the support structure. In one implementation, the structure attached to is bone. Additionally, the support structure can include a top surface, a bottom surface and two receivers, wherein each receiver includes an open-ended saddle type receiver configured for attachment to a medical device (e.g., screw assembly). The support structure can also include a locking means, to lock medical devices to the support structure after the support structure has been installed in a patient. The locking means can be setscrews or cams. Furthermore, the support structure in this implementation can include an anchor configured for attachment to a structure in a patient. In one implementation, the structure attached to in a patient is bone. Additionally, the anchor can be selected from the group consisting of a screw, staple, hook or a nail.

[0015] A method of use of one aspect of the invention for supporting the spine, can include the steps of: 1) delivering to bone, two screw assemblies having arms, bases and interconnection means; 2) delivering to the vicinity of bone, a support structure having two receivers having locking means for the arms of the screw assemblies; 3) deploying the arms of the screw assemblies; and 4) engaging the locking means of the receivers to secure the arms of the screw assemblies to the support structure.

[0016] Another method of use of one aspect of the invention for supporting the spine, can include the steps of: 1) delivering to bone, two screw assemblies having arms, bases and an interconnection means; 2) delivering to bone, a support structure having a central aperture with a locking means and an anchor, and two receivers having a locking means for the arms of the screw assemblies; 3) deploying the arms of the screw

assemblies; and 4) engaging the locking means of the receivers to secure the arms of the screw assemblies to the support structure.

[0017] Yet another method of use of one aspect of the invention for supporting the spine, can include the steps of: 1) delivering to bone, a screw assembly having an arm, a base and an interconnection means; 2) delivering to bone, a support structure having a central aperture with a locking means and an anchor, and a receiver having a locking means for the arm of a screw assembly; 3) deploying the arm of the screw assembly; and 4) engaging the locking means of the receiver to secure the arm of the screw assembly to the support structure.

[0018] In a further implementation, the medical device support structure can include an anchor, a receiver, and a locking means; wherein the anchor is configured for attachment to a structure in a patient. The receiver can include an open end for attachment to a medical device (e.g., a screw assembly). The locking means can be configured to lock the medical device to the support structure, after the support structure has been deployed in a patient. In one implementation, the structure is bone. The locking means can be a setscrew or a cam. The anchor can be selected from the group consisting of a screw, staple, hook or nail. In another implementation, the receiver can include a plurality of receivers for receiving medical devices.

[0019] In general, in another aspect, the invention features a medical device for supporting a structure comprising a screw assembly including a base and an arm. The arm can be a support configured for receiving one or more anchor assemblies that include a means for locking the anchor assemblies to the support. The support includes a top portion and a bottom portion, and an interconnection means for coupling the base to the support. The interconnection means allows the support to be positionable in a first position that is substantially parallel to a long axis of the base and secondarily positionable substantially perpendicular to the long axis of the base. The base and the one or more anchor assemblies are configured for attachment to a structure in a patient.

[0020] Implementations of one aspect of the invention can include one or more of the following features. The structure supported by the device can be bone selected from the group including a vertebra, femur, tibia, fibula, humerus, radius, ulna, calcaneus, and a pelvis.

**[0021]** The screw assembly of the device can have an overall length sized for subcutaneous support of the posterior of a spine.

**[0022]** The base of the screw assembly can be comprised of a base head having a shape and a locking means and an anchor. The base head shape can be an open saddle-type head. The locking means of the base can be comprised of a setscrew, wherein the setscrew is configured to link the support and the base, and wherein tightening the setscrew effects locking of the support in a position relative to a long axis of the base. The anchor of the base can be selected from the group including a screw, staple, nail, hook and a pin. In one embodiment, the anchor is a screw configured for bone anchoring. In another embodiment, the anchor is a screw configured for insertion into the pedicle of a vertebra.

**[0023]** The support of the device can have a shape selected from the group including a board, plate, elongated cross-section, oval, square, I-beam and a rod. The support can include a connector end, one or more apertures, and a receiver. The connector end can be configured for interconnection of the support and the base of the screw assembly. In one embodiment, the connector end is configured for hinge-type interconnection of the support and the base of the screw assembly.

**[0024]** The one or more apertures of the support can include a first connector end proximal aperture having a dimensional configuration to support a range of movement of the base in relation to the support. The apertures can further include one or more second connector end distal apertures for providing access to the base and the means for locking the anchor assembly to the support, when assembled with the support.

**[0025]** The support can include a support member having a top portion and a bottom portion, a head assembly, and an interconnection means. In one embodiment, the support member can include a receiver, and one or more apertures. The one or more apertures include a first aperture wherein an anchor assembly is passable therethrough and lockably engagable with the support member, and a second aperture wherein access is provided from the top portion of the support member to access the head assembly.

**[0026]** The head assembly of the support can include a connector end, an aperture having a dimensional configuration supporting a range of movement of the base in relation to the support, and a connector end proximal aperture having a dimensional



configuration to support a range of movement of the base in relation to the support. The head assembly can also include a locking means for securing the head assembly to the support member, wherein the head assembly is configured for interconnection with the support member.

[0027] In general in another aspect, the invention features a method of supporting a bony structure, the method including the steps of: 1) delivering to bone a screw assembly comprising a support having a receiver, a base, an interconnection means, and a locking means; 2) deploying the support substantially perpendicular to the long axis of the base; 3) passing through the support and implanting one or more anchor assemblies having a base and a locking means into bone; 4) locking the bases within one or more of the anchor assemblies; 5) locking one or more of the anchor assemblies within the support receiver; and 6) engaging the locking means of the screw assembly to secure the position of the support in relation to the base.

[0028] In general in a further aspect, the invention features a method of supporting a bony structure, the method comprising the steps of: 1) delivering to bone a screw assembly including: a support comprising a support member having a receiver, a head assembly having a connector end, an interconnection means and a locking means for securing the head assembly to the support member; a base; an interconnection means, and a locking means for securing the support in a position in relation to the base; 2) deploying the support substantially perpendicular to the long axis of the base; 3) passing through the support and implanting one or more anchor assemblies having a base and a locking means into bone; 4) locking the bases within one or more of the anchor assemblies; 5) locking one or more of the anchor assemblies within the support receiver; 6) locking the head assembly within the support member; and engaging the locking means of the screw assembly to secure the position of the support in relation to the base.

[0029] In general, in a further aspect, the invention features a medical device for supporting a structure including a screw assembly having a base, one or more arms, and an interconnection means for coupling the base to the one or more arms. The interconnection means allows the one or more arms to be positionable in a first position that is substantially parallel to a long axis of the base, and secondarily positionable substantially perpendicular to the long axis of the base. The base is configured for

attachment to a structure in a patient and the one or more arms are configured for attachment to one or more support structures.

**[0030]** Implementations of one aspect of the invention can include one or more of the following features. The structure in a patient can be bone. The screw assembly can have an overall length sized for subcutaneous support of the posterior of a spine. The base of the screw assembly can include a base head and an anchor.

**[0031]** The interconnection means of the screw assembly can include the base head of the screw assembly, and the base head can include a receiver and a setscrew. In one implementation, the setscrew secures the base to the one or more arms of the screw assembly. In another implementation, tightening the setscrew effects locking of the one or more arms in a position in relation to the base of the screw assembly. In one implementation, the interconnection means includes the base head of the screw assembly and the base head includes a hinge means.

**[0032]** The one or more arms of the device can include a body, wherein the body has an elongate shape and includes a connector end for attachment to a support structure, and a receiver end for connection to the base head receiver portion of the interconnection means. In one implementation, the elongate shape of the arm body can include an offset section, wherein the offset section is configured to provide a linear alignment of the base and the arm body when the arm is positioned substantially parallel to a long axis of the base. In another implementation, the elongate shape of the arm body is a shape configured for fitted interrelation between two or more arms positioned in a first position that is substantially parallel to a long axis of the base. In another implementation, the receiver end of the one or more arms and the receiver portion of the base head include a hinge means. In another implementation, a means is provided for locking the arm into a position substantially perpendicular to the long axis of the base. In one implementation, the means provided for locking the arm can include a one-way ratchet, a setscrew or a cam.

**[0033]** Implementations of one aspect of the invention can include one or more of the following features. The screw assembly of the device can include two arms and the receiver ends of the two arms can be configured for interconnection. In one implementation, one of the receiver ends of the two arms includes a first collet-type

receiver end having a substantially cylindrical recess, and the other receiver end of the two arms includes a substantially cylindrical shape for interconnection with the first collet-type receiver. In another implementation, one of the receiver ends of the two arms can include a first collet-type receiver end having a substantially spherical recess, and the other receiver end of the two arms can include a substantially spherical shape for interconnection with the first collet-type receiver.

[0034] In one implementation, the invention can include the following feature. The one or more support structures of the device can include an anchor, an aperture configured for attachment of an arm of the screw assembly, and a locking means configured to lock the arm of the screw assembly to the support structure.

[0035] In another implementation, the invention can include the following feature. The interconnection means of the screw assembly can include a hinge, a pin or a collet.

[0036] In general, in another aspect, the invention features a method of supporting the spine, the method comprising the steps of: 1) delivering to bone a screw assembly having one or more arms, a base and an interconnections means; 2) delivery to flanking bone one or more support structures having an aperture and locking means for the arms of the screw assembly; 3) deploying the one or more arms of the screw assembly to the flanking support structures; 4) locking the one or more arms of the screw assembly in a desired position; and 5) engaging the locking means of the support structure aperture.

[0037] Aspects of the invention may include one or more of the following advantageous features. In various implementations of the invention the support and screw assembly can be pre-loaded together. As such there is no need to connect the support and screw assembly at the surgical site. Use of the invention requires few user manipulations. For example, the screw assembly can first be inserted into the pedicle of a vertebrae. Next, the support which is connected by an interconnection means to the screw assembly can be deployed to a desired position. Subsequently, one or more anchor assemblies can be added to the support for attachment to additional vertebrae.

[0038] In various implementations of the invention the offset section of the arm body can be configured to provide a low-profile to the screw assembly when the one or more arms are positioned substantially parallel to a long axis of the base. The low profile is advantageous since it facilitates placement of the screw assembly and arms of the

device as a single unit, in a minimally invasive manner, through for example, a narrow access channel, port or cannula.

[0039] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

### DESCRIPTION OF DRAWINGS

[0040] FIG. 1A is a drawing of a screw assembly showing the screw assembly, arm and base in a first position.

[0041] FIG. 1B is a drawing showing the screw assembly in a second position.

[0042] FIG. 1C is a drawing showing the screw assembly including a press-fit cross pin-type interconnection means.

[0043] FIG. 1D is a drawing showing an open saddle-type base head.

[0044] FIG. 1E is a drawing showing an integrally disposed crosspiece.

[0045] FIG. 1F is a drawing showing a press-fit cross pin.

[0046] FIG. 2A is a drawing showing a support structure.

[0047] FIG. 2B is a drawing showing the support structure including a central aperture and an anchor.

[0048] FIG. 2C is a drawing showing the support structure including a hinged claw.

[0049] FIG. 3A is a drawing showing two screw assemblies connected by a support structure.

[0050] FIG. 3B is a drawing showing two screw assemblies connected by a support structure implanted into the pedicles of the vertebrae of the spine.

[0051] FIG. 4 is a drawing showing one screw assembly connected to a support structure having a central aperture and an anchor.

[0052] FIG. 5 is a drawing showing one screw assembly connected to a base having an open saddle-type head.

[0053] FIG. 6 is a drawing showing cannulas and a support structure tool used for implanting the screw assembly and support structure.

[0054] FIG. 7 is a drawing of a screw assembly tool used for manipulating the screw assembly during implantation of the screw assembly in the spine.

[0055] FIG. 8A is a drawing of a support assembly.

[0056] FIGS. 8B-C are drawings of a screw assembly having a base and a support, illustrating the interconnection between the base and the support such that the support is positioned substantially parallel (FIG. 8B) or perpendicular (FIG. 8C) to a long axis of the base.

[0057] FIG. 8D is a drawing of a support.

[0058] FIG. 9A is a drawing of an alternative support assembly.

[0059] FIGS. 9B-9E are drawings of a screw assembly.

[0060] FIG. 10A is a drawing showing a cutaway view of an anchor assembly prior to being secured within the support.

[0061] FIG. 10B is a drawing showing a cutaway view of an anchor assembly after being secured within the support.

[0062] FIG. 11A-11C are drawings of a screw assembly.

[0063] FIG. 11D is a cross-sectional drawing of a screw assembly.

[0064] FIG. 11E is a drawing of a screw assembly.

[0065] FIGS. 12A and 12B are cross-sectional drawings of a screw assembly.

[0066] FIG 12C is a drawing of a screw assembly showing a spherical-shaped collet-type connection between two arms and a cross-sectional view of a base.

[0067] FIG 12D is a cross-sectional drawing of a screw assembly showing a spherical-shaped collet-type connection between two arms.

[0068] FIG 13A is a drawing of a support assembly showing a screw assembly having one arm and a base attached to a support structure.

[0069] FIG 13B is a drawing of a support assembly showing a screw assembly having two arms and a base attached to two support structures.

[0070] FIG 14 is a drawing showing a support assembly implanted into the pedicles of the vertebrae of a spine.

[0071] Like reference symbols in the various drawings indicate like elements.

### **DETAILED DESCRIPTION**

[0072] As shown in FIGS. 1A and 1B, a screw assembly 1 is provided comprised of an arm 2 and a base 3 in a single unit. The screw assembly 1 is elongate and the arm 2 and base 3 of the screw assembly 1, are coupled by an interconnection means 4. Additionally, as shown in FIGS. 1A and 1B, the interconnection means 4 facilitates movement between the arm 2 and the base 3, such that the arm 2 is positionable in a first position that is parallel to a long axis of the base 3 (shown in FIG. 1A) and positionable in a second position that is perpendicular to the long axis of the base 3 (shown in FIG. 1B). The base 3 of the screw assembly 1 is configured for attachment to a structure (e.g., a bone) and the arm 2 is configured for attachment to a support structure 10 (described in detail below). In application, one or more screw assemblies 1 are attached to a support structure 10 (not shown). Preferably, two screw assemblies 1 are attached to a single support structure 10.

[0073] In an alternative screw assembly 1 implementation, the arm 2 and base 3 of the screw assembly 1 are configured as one continuous piece of shape memory metal. In this implementation, the interconnection means 4 is comprised of a shape memory

metal that can facilitate movement of the arm 2 relative to the base 3 depending on preset conditions affecting the shape memory metal shape (not shown). In another alternative screw assembly 1 implementation, the arm 2 and base 3 of the screw assembly 1 are configured as one continuous piece wherein the interconnection means 4 between the arm 2 and base 3 is comprised of a material suited for bending (not shown).

[0074] As shown in FIG. 1A, in certain embodiments, the arm 2 feature of the screw assembly 1 is comprised of a body 17, base yoke 18 and a connector end 12. The body 17 of the arm 2 can vary in shape and length with the application. In one implementation, the body 17 of the arm 2 is rod-shaped (see FIGS. 1A and 1B). Alternatively, the arm 2 body 17 is shaped to substantially fit within a screw assembly tool for manipulating the screw assembly 1. An example of such a screw assembly tool 19 is illustrated in FIG. 7.

[0075] The screw assembly 1 can be made of numerous materials that are durable and that can be implanted in a body, including titanium, stainless steel, carbon fiber, biocompatible material, etc. In one implementation, the screw assembly 1 is made of titanium. Additionally, the screw assembly 1 can be made of a reabsorbable material or shape memory metal. Alternatively, the screw assembly 1 can be a composite or combination of any of the foregoing. The dimensions of the screw assembly 1 vary with the application. In general, the length of the screw assembly 1 is from 0.1 to 100 centimeters. In one implementation, the length is substantially between 50 and 600 millimeters. In another implementation, the screw assembly 1 is sized for applications involving support of the posterior of the spine 28 (see FIG. 3B).

[0076] As shown in FIG. 1A, the base 2 of the screw assembly 1 is comprised of a base head 20 and an anchor 14. The anchor 14 can be a screw, staple, hook or nail and can be of a type typically used for bone anchoring. In one implementation the anchor 14 is a screw of a type for insertion into a pedicle 26 of a vertebrae 27 (see FIG. 1A and 3B).

[0077] As shown in FIG. 1C, the interconnection means 4 of the screw assembly 1 of FIG. 1A can be a press-fit cross pin type. In this implementation, the base head 20 is a press-fit cross pin-type head 5, and the yoke 18 of the arm 2 includes a pin hole 25, wherein the arm 2 and base 3 are pre-assembled including a press-fit cross pin (not shown) and a setscrew 9 (not shown). In an alternative implementation, as shown in

FIGS. 1D-F, the interconnection means 4 of FIG. 1A is configured as an open saddle head with coupling-cross piece. In this implementation, the base head 20 is configured as an open saddle-type head 6 (shown in FIG. 1D), which is pre-assembled with a complementary arm 2 feature. As shown in FIG. 1E, the arm 2 feature that is complementary to the open saddle-type head 6 can be a one-piece integrally disposed crosspiece 7. Alternatively, as shown in FIG 1F, the complementary arm 2 feature can be a press-fit cross pin 8.

[0078] As shown in FIGS. 1A and 1B, the arm 2 and base 3 can be held together as a single unit by the set screw 9 where the interconnection means 4 is of the form of a press-fit cross pin-type or an open saddle-type head with a coupling cross piece. In certain implementations, the open saddle-type head is threaded to receive the setscrew 9.

[0079] Additionally, as shown in FIGS. 1A and 1B, the setscrew 9 can effect locking of the arm 2 into a fixed position. Prior to moving the arm 2 into the deployed position, the setscrew 9 is loosely set in place. Upon deployment, the arm 2 can be locked in a position that is substantially perpendicular to the long axis of the base 3 by tightening the setscrew 9 into the threaded open saddle head 6 of the base 3 (see FIG. 1D).

[0080] In one implementation, locking of the arm 2 position and holding the arm 2 and base 3 together as a single unit can be achieved using a cam rather than a setscrew 9 (not shown). Where a cam is substituted for a setscrew 9, locking of the arm 2 and joining of the arm 2 and the base 3 is achieved by an analogous means.

[0081] Referring now to FIGS. 2A-C, 3A, 3B and 4, a support structure 10 is shown to which the connector end 12 of the arm 2 of the screw assembly 1 can be attached (see FIGS. 3A, 3B and 4). As shown in FIG. 2A, the support structure 10 is comprised of a top surface 15, a bottom surface 16, and one or more open-ended saddle receivers 11 including a setscrew 9, or, in the alternative, a cam, for locking. The receiver 11 is shaped to accommodate the connector end 12 of the arm 2 of the screw assembly 1. As shown in FIGS. 2A and 2B, the setscrew 9 is threaded into the support structure 10, perpendicular to the plane of the top surface 15 of the support structure 10, to facilitate access to the setscrew 9 from above the support structure 10. In one implementation, the support structure 10 is comprised of two receivers 11 (see FIGS. 2A-C, 3A, 3B and 4), whereby two screw assemblies 1 can be linked together via the support



structure 10 (see FIG. 3A). In another implementation, as shown in FIG. 3B, two screw assemblies 1 linked together via the support structure 10 can be implanted into the pedicles 26 of vertebrae 27 in a spine 28 to effect support of the spine 28.

[0082] As shown in FIGS. 2B and 4, the support structure 10 can be configured to additionally include a central aperture 13 that passes from the top surface 15 of the support structure 10 through to the bottom surface 16 of the support structure 10. As shown in FIGS. 2B and 4, the central aperture 13 can be threaded to accommodate an anchor 14 and optionally include a setscrew 9 or a cam for locking the anchor 14 in position. In this implementation the threading of the central aperture 13, and receiver 11 setscrew(s) 9, are both aligned perpendicularly to the top surface 15 of the support structure 10. The anchor 14 can be a screw, staple, hook or nail and be of a type typically used for bone anchoring. In one implementation, the anchor 14 is a screw of a type for insertion into the pedicle of a vertebrae.

[0083] In another implementation, as shown in FIG. 2C, the support structure 10 can optionally include a hinged claw 21 for clamping the support structure 10 onto a surface (e.g., a bony surface). The claw 21 features a hinge 22 positioned between two receivers 11 in the support structure 10. The claw 21 includes a threaded engagement member 23 extending above the top surface 15 of the support structure 10, whereby upon threading a nut (not shown) over the engagement member 23, a pivoting about the hinge 22 is effected and the claw 21 closes.

[0084] The support structure 10 can be made of numerous materials that are durable and that can be implanted within a body, including titanium, stainless steel, carbon fiber, biocompatible material, etc. Preferably, the screw assembly 1 is made of titanium. Additionally, the support structure 10 can be made of a reabsorbable material. Alternatively, the support structure 10 can be a composite or combination of any of the foregoing.

[0085] As shown in FIG. 5, another implementation of the invention includes a single screw assembly 1, connected to a support structure 10 having a receiver 11, an anchor 14 and a locking means. In one implementation the receiver 11 is configured as an open saddle-type head 6. In another implementation, the support structure 10 includes a plurality of receivers 11. The locking means can include a setscrew 9 or alternatively a

cam. In one implementation, the connector end 12 of the screw assembly arm 2 is locked into the open saddle-type receiver head 6 of the support structure 10 after the anchor is installed in a patient.

[0086] As shown in FIG. 6, a method of using the invention to support the spine 28 includes the steps of: 1) making a series of small incisions along the spine 28 to provide cannula 29 access to the pedicle 26 portions of a series of vertebrae 27; 2) using the cannula 29 access route, deliver two un-deployed screw assemblies 1 to a series of pedicles 26 and screw them into respective pedicles 26 (wherein un-deployed refers to a configuration of the screw assemblies such that each arm is set in a position that is parallel to the long axis of the base); 3) using the cannula 29 access route and a support structure tool 30, deliver, screw into place and lock a support structure 10 having a central aperture, set screw, two receivers with setscrews and pedicle screw-type anchor; 4) deploy the arms of each screw assembly 1 substantially perpendicular to the long axis of the base; 5), and engage and lock into place each connector end of each arm within the support structure 10 receivers using the set screws.

[0087] The above method includes the use of a special screw assembly tool 19 for manipulation of the screw assemblies 1 (see FIG. 7). The screw assembly tool 19 includes an inner cavity 24 configured to accommodate the un-deployed screw assembly within it. In use, the screw assembly tool 19 facilitates the insertion of the un-deployed screw assembly base into a structure (e.g., bone) from within the confines of a cannula 29 (see FIG. 6).

[0088] An additional method of use of the invention for supporting the spine, can include the steps of: 1) delivering to bone, two screw assemblies having arms, bases and interconnection means; 2) delivering to the vicinity of bone, a support structure having two receivers having locking means for the arms of the screw assemblies; 3) deploying the arms of the screw assemblies; and 4) engaging the locking means of the receivers to secure the arms of the screw assembly to the support structure.

[0089] Another method of use of the invention for supporting the spine, can include the steps of: 1) delivering to bone, two screw assemblies having arms, bases and an interconnection means; 2) delivering to bone, a support structure having a central aperture with a locking means and an anchor, and two receivers having locking means for

the arms of the screw assemblies; 3) deploying the arms of the screw assemblies; and 4) engaging the locking means of the receivers to secure the arms of the screw assemblies to the support structure.

[0090] Yet another method of use of the invention for supporting the spine, can include the steps of: 1) delivering to bone, a screw assembly having an arm, base and interconnection means; 2) delivering to bone, a support structure having a central aperture with a locking means and an anchor, and a receiver having locking means for the arm of a screw assembly; 3) deploying the arm of the screw assembly; and 4) engaging the locking means of the receiver to secure the arm of the screw assembly to the support structure.

[0091] As shown in FIGS. 8A and 9A, a screw assembly 101 is provided comprising a base 102, a support 103 configured for receiving one or more anchor assemblies 301 and an interconnection means 105 between the base 102 and the support 103. As shown in FIGS. 8A, 8C, 8D and 9A-9E, the support 103 includes a top portion 107 and a bottom portion 108 (see FIGS. 8B, 8C, 9D and 9E). The interconnection means 105 allows the support 103 to be positionable in a first position that is substantially parallel to a long axis of the base 102 (see FIGS. 8B, 9B-9D) and secondarily deployed or positioned substantially perpendicular to the long axis of the base 102 (see FIGS. 8A, 8C, 9A and 9E). The base 102 of the screw assembly 101 and the one or more anchor assemblies 301 are configured for attachment to a structure (e.g. bone) in a patient. In application, a screw assembly 101 receives one or more anchor assemblies 301 to form a support assembly 106 (see FIGS. 8A and 9A). In one implementation, the anchor assembly 301 is combined with the screw assembly 101 after deployment of the support 103 (forming support assembly 106) and in another implementation, the anchor assembly 301 is pre-assembled with the screw assembly 101. One advantage of the invention over the prior art solutions is timesavings when using the support assembly 106 for supporting a structure. Another advantage is relative ease of removal. The support assembly 106 can be used for temporary or permanent implantation.

[0092] The support assembly 106, once assembled, can be used to support a bony structure. The bony structure supported can include a femur or other bones of the leg (e.g. tibia and fibula), bones of the arm and wrist (e.g. humerus, radius and ulna), and other bones such as the calcaneous, pelvis, spine (vertebrae) and the like. Support can be

provided for a single bone (i.e. a long bone such as the femur, tibia, humerus) or for more than one bone (i.e. vertebrae).

[0093] The screw assembly 101 can be made of materials that are durable and that can be implanted in a body, including titanium, stainless steel, carbon fiber, etc. In one implementation, the screw assembly 101 is made of titanium. In another implementation the screw assembly 101 is made of a biocompatible material, a reabsorbable material or a combination of any of the foregoing materials. The dimensions of the screw assembly 101 vary with the application. In general, the length of the screw assembly 101 is from 20 to 1,000 millimeters. In one implementation, the length is substantially between 50 and 400 millimeters. In another implementation, the screw assembly 101 is sized for applications involving support of the posterior of the spine (not shown).

[0094] As shown in FIGS. 8A-8C, 9A-9E and 10A-10B, the base 102 of the screw assembly 101 is comprised of a base head 114 having a shape and a locking means, and an anchor 109a. The shape of the base head 114 can be comprised of any of a number of shapes suitable for receiving or interconnecting with the support 103. In one implementation, the base head 114 shape is an open saddle-type head. As shown in FIGS. 8A, 8C and 9A, in one implementation, the locking means of the base head 114 can be a setscrew 104. The setscrew 104 can be configured to link the support 103 and the base 102 while permitting a freedom of movement between the base 102 and the support 103 (see FIGS. 8A, 9A and 9E). The locking means can effect locking of the support 103 in a position relative to the base 102. In one implementation the setscrew 104 can be tightened to effect locking of the support 103 in a position relative to (for example, the long axis of) the base 102. In an alternative implementation, the locking means of the base head 114 can be a cam (not shown).

[0095] As shown in FIGS. 8A-8C, 9A-9E and 10A-10B, the anchor 109a of the screw assembly 101 is can be selected from the group consisting of a screw, staple, nail, hook and pin. In one implementation, the anchor 109a is configured for bone anchoring. In another implementation, the anchor 109a is a screw configured for insertion into the pedicle of a vertebra.

[0096] As shown in FIGS. 8A, 9A and 10A-10B, the anchor assembly 301 is configured to interconnect with the shape of the receiver 306 (discussed in detail below).

The anchor assembly 301 shape can be any of a number of shapes. In some implementations, the mating between the support 103 and the anchor assembly 301 occurs only in two dimensions (e.g. where a 90 degree twisting receiver 306 is employed). As shown in FIGS. 10A-10B, the anchor assembly 301 can be comprised of a head 302, a base 109b and a base head 114. The anchor assembly 301 can be comprised of numerous materials that are durable and that can be implanted in a body, including titanium, stainless steel, carbon fiber, etc. Additionally, the anchor assembly 301 can be comprised of a reabsorbable material or a biocompatible material, or a combination of any of the foregoing materials.

[0097] As shown in FIGS. 10A -10B, the anchor assembly 301 includes a means for locking the anchor assembly 301 to the support 103. In one implementation, as shown in FIG. 10A, where the receiver 306 and complimentary head 302 of the anchor assembly 301 are T-slot shaped, the means for locking the anchor assembly 301 can be a setscrew 104 threaded into the head 302 of the anchor assembly 301, wherein the head 302 includes a threaded base aperture 305 and a deformable geometry. Such a means for locking an anchor assembly 301 to the support 103 is disclosed in the commonly owned U.S. Application Serial No. 11/019,918. As shown in FIG. 10B, when the setscrew 104 is turned into the threaded base aperture 305, the deformable head 303 is caused to splay outward such that the T-slot shape of the head 302 engages and locks against the receiver 306 planar medial face 308. As shown in FIGS. 10A and 10B, the setscrew 104 can be disposed such that it is constrained within the threaded base aperture 305. The constrained setscrew 104 upon final tightening can be over-constrained thereby forcing the deformable head 303 to splay outward. In another implementation, the head 302 may additionally engage the receiver 306 planar upper face 309 or planar lower face 307 or both to effect locking. In another implementation, a cam can be substituted for the setscrew 104 to effect the locking of the anchor assembly 301 within the support 103 (not shown).

[0098] The deformable geometry of the deformable threaded base aperture 305 can be comprised of a void within the anchor assembly 301 head 302 wherein the void is selected from the list consisting of a cavity, slot notch, groove, cut out, gap and a recess. In one implementation, the void is tapered. In another implementation as shown in FIGS.

9A and 9A, the void within the anchor assembly 301 head 302, can be a slot 313 cut into the head 302.

[0099] Other means for locking an anchor assembly 301 to the support 103 are possible, including those disclosed in U.S. Application Serial No. 10/826,684, filed April 16, 2004, entitled "Subcutaneous Support".

[00100] As shown in FIGS. 10A-10B, the anchor assembly 301 includes a base 102 moveably disposed within the threaded base aperture 305. The base 102 can be a screw, staple, hook or nail and of a type typically used for anchoring to a structure (e.g., to a bone). In one implementation, the base 102 is a screw of a type for insertion into the pedicle of a vertebra. In another implementation, the base 102 can be attached to another bony structure.

[00101] Attachment of the base 102 to the anchor assembly 301 can be accomplished in numerous ways. In one implementation, the attachment is through a hinge-type of connection between the base 102 and the anchor assembly 301 (see, e.g., as in FIGS. 1A-1B). In another implementation, as shown in FIGS. 10A-10B, the attachment is made between a polyaxial-type base head 114 on the base 102 and a complimentary receptacle 304 within the anchor assembly 301 head 302.

[00102] The anchor assembly 301 further includes a means for locking the base 102 within the anchor assembly 301 head 302. As shown in FIGS. 10A-10B, for a polyaxial-type base head 114, the means for locking can include a setscrew 104 disposed within a threaded base aperture 305. In this configuration, turning the setscrew 104 causes the setscrew 104 to press directly against the polyaxial base head 114 of the base 102, thereby forcing it against the receptacle 304 of the anchor assembly 301 to effect locking. Alternatively, where the base 102 is of the hinge-type, the means for locking can be comprised of a setscrew 104 disposed in a threaded base aperture 305. In this configuration, turning the setscrew 104 causes the setscrew 104 to press directly against the base head 114 of the hinge-type base 102, thereby creating friction against the hinge's pin to effect locking (not shown). In another implementation, a cam can be substituted for the setscrew 104 to effect locking.

[00103] As shown in FIGS. 10A-10B, another implementation of the anchor assembly 301 includes a longitudinal aperture 312 through the base 102 and base head

114, a tool interface 311 and a setscrew aperture 310. The longitudinal aperture 312 and setscrew aperture 310 are configured such that an instrument, wire (e.g. a K-wire) or other guide can pass through the entire anchor assembly 301. The setscrew aperture 310 is further configured such that a tool or instrument can pass through the setscrew aperture 310 to engage the tool interface 311 of the base 102. Alternatively, the setscrew 104 can be a cam (not shown).

[00104] The setscrew aperture 310 can be any shape and can be sized to accommodate the through passage and use of objects and tools without affecting the positioning of the setscrew 104.

[00105] The longitudinal aperture 312 can have any desired cross-sectional shape including but not limited to round, square, hexagonal, oval or any regular or irregular shape.

[00106] The tool interface 311 can be any shape suitable for receiving a tool for manipulating the base 102. For example, where the base 102 is a screw, the tool interface 311 can be a hex shape, or any other commonly used screw head tool interface shape.

[00107] Where an anchor assembly 301 is configured as shown in FIGS. 10A-10B, the setscrew 104 can be pre-positioned within the base aperture 305 without being tightened. The setscrew aperture 310 and longitudinal aperture 312 (passing through the base 102 and base head 114) enable access through a pre-assembled implementation of the anchor assembly 301. Additionally, wherein the anchor assembly 301 is pre-assembled, access is provided to the tool interface 311 of the base head 114 through the setscrew aperture 310.

[00108] As shown in FIGS. 8A, 8D, 9A, 9D and 9E, the support 103 has a shape. The shape of the support 103 can be selected from the group consisting of a board, plate, elongated cross-section, oval, square, I-beam and a rod. In one implementation, as shown in FIGS. 8A, 8D, 9A, 9D and 9E, the support is shaped as a plate. In one implementation, the length of the support 103 is minimally substantially the same length as required to span two or more vertebrae. In one implementation, the support 103 is substantially a length as required to span three vertebrae. In another implementation, the length of the support 103 is substantially between 25 to 140 millimeters.

[00109] As shown in FIGS. 8A-8D, in one implementation the support 103 is comprised of a connector end 110, one or more apertures 111, and a receiver 306. The connector end 110 is configured for interconnection of the support 103 and the base 102 of the screw assembly 101. In one implementation, the connector end 110 is configured for hinge-type interconnection of the support 103 and the base 102 of the screw assembly 101.

[00110] As shown in FIGS. 8A, 8B, and 8D, in one implementation the one or more apertures 111, of the support 103 include a first aperture 111c positioned proximal to the connector end 110, and a second aperture 111a positioned distal to the connector end 110, in relation to the support 103. As shown in FIGS. 8A, 8B and 8D, the first aperture 111c, can provide for a range of movement for the base 102 in relation to the support 103. In one implementation, the movement of the base 102 in relation to the support 103 includes a hinge-type of movement (see FIGS. 8A-8C). As shown in FIG. 8A, the second aperture 111a can provide for access to the base 103 and the means for locking the anchor assembly 301 to the support 103, when the anchor assembly 301 is assembled with the support 103. In one implementation, the second aperture 111a can provide for access to the support 103 from above after the support 103 is deployed into a position that is substantially perpendicular to the base 102.

[00111] As shown in FIGS. 8A and 8D, in one implementation, the receiver 306 is disposed within a long axis of the support 103. In another implementation, the receiver 306 is connected to the top portion 107 or the bottom portion 108 of the support 103. In an additional implementation, the receiver 306 substantially spans the length of the support 103. The configuration of the receiver 306 can be comprised of any of a number of designs and shapes. In one implementation, the receiver 306 has a configuration selected from the group consisting of a slot, groove, track, dovetail and a snap-in configuration. In another implementation, the receiver 306 has a 90-degree twist-in configuration. In yet another implementation, the receiver 306 and the anchor assembly 301 are both configured in an interconnecting geometry comprising a T-slot (see FIGS. 10A and 10B). As shown in FIGS. 10A and 10B, in one implementation, the T-slot configuration of the receiver 306 can be comprised of a planar upper face 309, a planar lower face 307 and a planar medial face 308. The receiver 306 can include two ends wherein one or both ends are open or closed (not shown).



[00112] As shown in FIGS. 9A-9E, in one implementation the support 103 is comprised of a support member 202, a head assembly 201 and an interconnection means 105 (for example, a slot-flange combination). The support member 202 can include a top portion 107 and a bottom portion 108 and one or more apertures 111 (see FIGS. 9A-9E). As shown in FIGS. 9A-9C, in one implementation the support member 202 includes a receiver 306 and one or more apertures 111.

[00113] As shown in FIG. 9A, in one implementation, the receiver 306 is disposed within a long axis of the support member 202. In another implementation, the receiver 306 is connected to the top portion 107 or the bottom portion 108 of the support member 202 (for example, as an attachment). In an additional implementation, the receiver 306 substantially spans the length of the support member 202. The configuration of the receiver 306 can be comprised of any of a number of designs and shapes. In one implementation, the receiver 306 has a configuration selected from the group consisting of a slot, groove, track, dovetail and a snap-in configuration. In another implementation, the receiver 306 has a 90-degree twist-in configuration. In yet another implementation, the receiver 306 and the head assembly 201 are both configured in an interconnecting geometry comprising a T-slot (see FIGS. 10A and 10B). As shown in FIGS. 10A and 10B, in one implementation, the T-slot configuration of the receiver 306 can be comprised of a planar upper face 309, a planar lower face 307 and a planar medial face 308.

[00114] The receiver 306 can include two ends wherein a first end is open and second end is closed (not shown). Alternatively, both ends can be open or both ends can be closed (not shown).

[00115] As shown in FIGS. 9A-9C, in one implementation the one or more apertures 111, of the support member 202 include a first aperture 111a wherein an anchor assembly 301 is passable therethrough and lockably engagable with the support member 202. A second aperture 111b can be included wherein access is provided from the top portion 107 of the support member 202, through to the bottom portion 108 of the support member 202 (see FIGS. 9A-9C). As shown in FIGS. 9B and 9C, the second aperture 111b can also provide access to the head assembly 201 of the support 103 when the head assembly 201 is interconnected with the support member 202.

[00116] As shown in FIGS. 9A – 9C, in one implementation the head assembly 201 is configured for interconnection with both the support member 202 and the base 102. The head assembly 201 includes a connector end 110, an aperture 111c and a locking means (for example, a flange) for securing the head assembly 201 to the support member 202. In one implementation the receiver 306 of the support member 202 and the head assembly 201 are configured in an interconnecting geometry comprising a T-slot. The interconnecting geometry between the head assembly 201 and the support member 202 can provide for adjustable positioning (and/or locking) of the support member 202 along the long axis of the head assembly 201 (see FIGS. 9B and 9C). As shown in FIG. 9B, the head assembly 201 can be contracted within the support member 202 to reduce the overall length of the screw assembly 101. In contrast, as shown in FIG. 9C, the head assembly 201 can be extended in relation to the support member 202 to increase the overall length of the screw assembly 101.

[00117] The connector end 110 of the head assembly 201 can be configured for interconnection of the support 103 and the base 102 of the screw assembly 101. In one implementation, the connector end 110 is configured for hinge-type interconnection of the support 103 and the base 102 of the screw assembly 101 (see FIGS. 9A-9E).

[00118] As shown in FIGS. 9A – 9C, the aperture 111c of the head assembly can have a dimensional configuration to support a range of movement of the base 102 in relation to the support 103. Also as shown in FIGS. 9A – 9C, the locking means for securing the head assembly 201 to the support member 202 can be comprised of a setscrew 104 disposed within the head assembly 201. In use, turning the setscrew 104 can result in contact between the setscrew 104 and the support member 202, thereby providing a means to secure the head assembly 201 to the support member 202. Alternatively, in another implementation, the locking means for securing the head assembly 201 to the support member 202 can be comprised of a cam.

[00119] A method of use of the invention for supporting a bony structure, can include the steps of: 1) delivering to bone a screw assembly comprising a support having a receiver, a base, an interconnection means, and a locking means; 2) deploying the support substantially perpendicular to the long axis of the base; 3) passing through the support and implanting one or more anchor assemblies having a base and a locking means into bone; 4) locking the bases within one or more of the anchor assemblies; 5) locking

one or more of the anchor assemblies within the support receiver; and 6) engaging the locking means of the screw assembly to secure the position of the support in relation to the base.

[00120] In a further implementation, the method of use described above can include disposing the support adjacent to bone or adjacent to a spine. In one implementation, the method of use described above can include disposing the support with the subcutaneous fat layer of the back. In another implementation, the method of use described above can include disposing the support external to the body.

[00121] Another method of use of the invention for supporting a bony structure, can include the steps of: 1) delivering to bone a screw assembly comprising: a support comprising a support member having a receiver, a head assembly having a connector end and an interconnection means; a base; an interconnection means, and a locking means; 2) deploying the support substantially perpendicular to the long axis of the base; 3) passing through the support and implanting one or more anchor assemblies having a base and a locking means into bone; 4) locking the bases within one or more of the anchor assemblies; 5) locking one or more of the anchor assemblies within the support receiver; 6) locking the head assembly within the support member; and 7) engaging the locking means of the screw assembly to secure the position of the support in relation to the base.

[00122] In one implementation, the method of use described above can include disposing the support adjacent to bone or adjacent to a spine. In one implementation, the method of use described above can include disposing the support with the subcutaneous fat layer of the back. In another implementation, the method of use described above can include disposing the support external to the body.

[00123] A method of use of the invention for effecting a desired vertebral disk spacing, can include the steps of: 1) implanting a screw assembly comprising a support having a receiver, a base, an interconnection means, and a locking means into a vertebra; 2) deploying the support substantially perpendicular to the long axis of the base; 3) passing through the support and implanting one or more anchor assemblies having a base and a locking means into a vertebra; 4) interconnecting the anchor assembly with the receiver of the support, wherein the anchor assembly is unlocked within the receiver; 5) compressing or distracting the base of the screw assembly and the base of the anchor

assembly in relation to each other (e.g. to achieve a parallel displacement of the instrumented vertebrae (); 6) locking the anchor assembly within the support (e.g. using a setscrew or cam); and 7) locking the support position in relation to the base using the screw assembly locking means (e.g. using a setscrew or cam).

[00124] The term “instrumented” as used herein defines a physical connection between a structure (e.g. a vertebra) and a medical device or instrument.

[00125] A method of use of the invention for effecting a desired curvature of the spine can include the steps of: implanting a screw assembly comprising a support having a receiver, a base, an interconnection means, and a locking means into a vertebra; 2) deploying the support substantially perpendicular to the long axis of the base; 3) passing through the support and implanting one or more anchor assemblies having a base and a locking means into a vertebra; 4) interconnecting the anchor assembly with the receiver of the support, wherein the anchor assembly is unlocked within the receiver; 5) compressing or distracting the bases in relation to each other (e.g. to affect the lordotic/kyphotic curvature of the spine); 6) locking the anchor assembly within the support (e.g. using a setscrew or cam); and 7) locking the support position in relation to the base using the screw assembly locking means (e.g. using a setscrew or cam).

[00126] As shown in FIGS. 11A –11C and 11E, a screw assembly 1101 is provided including a base 1102 and one or more arms 1103 in a single unit. The arm 1103 and base 1102 of the screw assembly 1101 are coupled by an interconnection means. The base 1102 of the screw assembly 1101 is configured for attachment to a structure (e.g., a bone) and the arm 1103 is configured for attachment to a support structure (described in detail below). In application, a screw assembly 1101 having one or more arms 1103 is attached to one or more support structures to form a support assembly 1301 (see FIGS. 13A and 13B). The support assembly 1301 can be used for temporary or permanent implantation.

[00127] As shown in FIGS. 11A and 11B, the screw assembly 1101 interconnection means can facilitate free-rotational (or multiaxial) movement of an arm 1103 in relation to the base 1102. The interconnection means can be selected from any number of means including but not limited to: a hinge means, a collet means, and a pin. As shown in FIGS. 11A and 11B, the interconnection means comprises a receiver end 1112 disposed within a receiver 1202 of a base 1102. In this implementation, the arm

1103 can have a substantially spherical-shaped receiver end 1112 connected to a complementary-shaped receiver 1202 in the base head 104. Additionally, the base head 1104 can be closed or open (e.g. open-saddle as shown in FIG. 1A). The free-rotational arm 1103 movement facilitated by the interconnection means is substantially a cone-shaped range of movement having an axis about which such movement is centered ("cone axis" hereinafter).

[00128] In use, the implementation as shown in FIGS. 11A and 11B can be used to provide support to a structure in a patient (e.g. a spine having a series of vertebrae). Where the structure supported is a spine, and the spine includes a long axis ("spinal axis" hereinafter), the screw assembly 1101 can provide support to the spine substantially collinearly with the spinal axis. Specifically, the cone axis of movement of the arm 1103 of the screw assembly 1101 can optionally be disposed so that the cone axis is substantially collinear with the spinal axis. This arrangement provides a degree of adjustability when positioning the arm 1103 and base 1102 of the screw assembly 1101 in relation to the structure being supported (e.g. a series of vertebrae). For example, where three sequential vertebrae are to be supported by a support assembly 1301 including a screw assembly 1101 having two arms 1103 and two support structures (described in detail below), the three points of attachment to the three vertebrae can be substantially linear. Alternatively, the three points of attachment are not necessarily substantially linear.

[00129] In another implementation, as shown in FIGS. 11C and 11E, the interconnection means comprises one or more receiver end(s) 1112 of one or more arm(s) 103 disposed within a base head 1104 of a base 1102. In this implementation the interconnection means can facilitate movement between the arm 1103 and the base 1102, such that the arm 1103 is positionable in a first position that is parallel to a long axis of the base 1102 (shown in FIGS. 11D, 12B, and 12D) and positionable in a second position that is perpendicular to the long axis of the base 1102 (shown in FIG. 11C and 11E). Additionally, the screw assembly 1101 interconnection means can facilitate free-rotational (or multiaxial) movement of an arm 1103 in relation to the base 1102. As discussed above, the free-rotational movement of the arm 1103 can be substantially a cone-shaped range of movement having a cone axis. In use, the implementation as shown in FIGS. 11C and 11E can be used to provide support to a structure in a patient (e.g. a spine having

a series of vertebrae). As discussed for the implementation described above and shown in FIGS. 11A and 11B, the present implementation can provide support to the spine substantially collinearly with the spinal axis. Optionally, as shown in FIGS. 12C and 12D, an implementation wherein support is provided substantially collinearly with the spinal axis can include a cone axis of movement of the arm 1103 of the screw assembly 1101 disposed so that the cone axis is substantially perpendicular with the spinal axis. This arrangement provides a similar degree of arm 1103 adjustability and advantages as discussed above for the implementation shown in FIGS. 11C and 11E.

[00130] The screw assembly 1101 can be made of materials that are durable and that can be implanted in a body, including titanium, stainless steel, carbon fiber, etc. In one implementation, the screw assembly 1101 is made of titanium. In another implementation the screw assembly 1101 is made of a biocompatible material, a reabsorbable material, or a combination of any of the foregoing materials. The dimensions of the screw assembly 1101 vary with the application. In general, in implementations as shown in FIGS. 11C and 11E, wherein the arm 1103 is positionable in a first position that is substantially parallel to the long axis of the base 1102, the length of the screw assembly 1101 is from substantially 20 to 1,000 millimeters. In one implementation, the length is substantially between 50 and 400 millimeters. In another implementation, the screw assembly 1101 is sized for applications involving support of multiples levels of the posterior of the spine (see FIG. 14). In another implementation, as shown in FIGS. 11A and 11B, the length of the base 1102 is from substantially 20 to 100 millimeters and the length of the one or more arms 1103 is from substantially 20 to 600 millimeters. In another implementation the length of the base 1102 and the length of the arm 1103 are each from substantially between 20 and 600 millimeters. In another implementation, the combined length of the base 1102 and the arm 1103 is sized for applications involving support of multiple levels of the posterior of the spine (see FIG. 14).

[00131] In one implementation, as shown in FIGS. 11D, 12B, and 12D, the screw assembly 1101 includes a longitudinal aperture 1106. The longitudinal aperture 1106 traverses the length of the screw assembly 1101, and provides an aperture for the passage of instruments, tools, and guides (e.g. a K-wire) when the arm 1103 is positioned in a first position that is parallel to a long axis of the base 1102 (see FIG. 1D, 2B, and 2D).

[00132] As shown in FIGS. 11A-11C and 11E, the base 1102 of the screw assembly 1101 is comprised of a base head 1104 and an anchor 1105. The anchor 1105 can be a screw, staple, hook, or nail, and can be of a type typically used for bone anchoring. In one implementation the anchor 1105 is a screw of a type for insertion into a pedicle of a vertebra (see FIGS. 11A-11C, 11E, 13A-13B and 14).

[00133] In one implementation, as shown in FIGS. 12A-12D, the interconnection means for coupling the base to the arms is comprised of the base head 1104. The base head 1104 can include a receiver 1202 for receiving the receiver ends 112 of the screw assembly arms 1103. In another implementation, the base head 1104 is configured for hinged attachment of one or more screw assembly arms 1103 using a hinge means (see, e.g., as in FIGS. 1A-1B)..

[00134] The base head 1104 can include a locking means. As shown in FIGS. 11A-11D and 12B-12D, the locking means can be a setscrew 1107. The base head 1104 can be designed to include an open-saddle (see FIGS. 11A and 11B) or closed configuration (see FIGS. 11C – 11E) for accommodating the locking means (e.g. a setscrew 1107). In one implementation, the locking means is a setscrew 1107, which secures the base 1102 and the one or more arms 1103 of the screw assembly 1101 together.

[00135] In use, a screw assembly 1101 including a base 1102, one or more arms 1103 and a locking means can be pre-assembled for delivery to a structure. Alternatively, the screw assembly 1101 can be delivered as separate pieces for assembly at the site of a structure.

[00136] As shown in FIGS. 11A, 11B, 11D and 12B-12D, tightening the setscrew 1107 can effect locking of one or more arms 1103 into a position in relation to the base 1102. In an implementation as shown in FIGS. 11D and 12B-12D, after one or more arms 1103 of a screw assembly 1101 are deployed from a first position that is substantially parallel to a long axis of the base to a second position that is substantially perpendicular to the long axis of the base 1102, the setscrew 1107 can be tightened to effect locking of the one or more arms 1103 in the second position. In an alternative implementation, a cam (not shown) can be substituted for the setscrew 1107.

[00137] In another implementation, as shown in FIG. 11A, wherein a single arm 1103 is connected to the base 1102, the setscrew 1107 can be tightened to effect locking of the arm 1103 into a position. In this implementation, the arm 1103 can have a substantially spherical-shaped receiver end 1112 connected to a complementary-shaped receiver 1202 in the base head 1104. The base head 1104 can be closed or open (e.g. open-saddle as shown in FIG. 11A). Tightening the setscrew 1107 can create a load that compresses the receiver end 1112 of the arm 1103 against the receiver 1202 to effect locking of the arm 1103 into a position. As shown in FIG. 12C, the receiver 1202 can be a substantially spherical collet-type receiver. In such an implementation, tightening the setscrew 1107 creates a load that compresses the receiver end 1201 of the arm 1103 against the receiver 1202, thereby deflecting one or more deformable fingers 1204 around the receiver end 1112 to effect locking of the arm 1103 into a position (see FIG. 12C).

[00138] In another implementation, as shown in FIG. 11B, wherein two arms 1103 are connected to the base 1102, the setscrew 1107 can be tightened to effect locking of both arms 1103 into a position. In this implementation, a first arm 1103 can include a substantially spherical collet-type receiver end 1201 and the second arm can include a receiver end 1112 configured to interconnect within the receiver end 1201 (see FIG. 12C and 12D). As shown in FIG. 12C, tightening the setscrew 1107 can create a load that compresses the receiver end 1201 of the first arm 1103 against the receiver end 1112 of the second arm 1103, thereby deflecting one or more deformable fingers 1204 of the receiver end 1201 around the receiver end 1112 of the second arm 1103 to effect simultaneous locking of both arms 1103 into a position.

[00139] The receiver end 1201 of the first arm 1103 and the receiver end 1112 of the second arm 1103 can also be configured to provide for step-wise locking of each arm 1103 into a position in relation to the base head 1104. For example, the receiver end 1201 of the first arm can be configured such that initial tightening creates a load that compresses the receiver end 1112 against the base head receiver 1202 to effect locking of the first arm 1103 into a position without affecting the free rotational movement of the second arm 1103. Upon final tightening, the increased load created thereby can compresses the receiver end 1201 of the first arm 1103 against the receiver end 1112 of the second arm 1103, thereby deflecting one or more deformable fingers 1204 of the



receiver end 1201 around the receiver end 1112 of the second arm 1103 to effect locking of the second arm 1103 into a position.

[00140] In another implementation, as shown in FIG. 11D, the setscrew 1107 can be tightened to effect locking of a single arm 1103 having a cylindrical shaped receiver end 1112, by creating a load that compresses the receiver end 1112 of the arm 1103 against the complementary-shaped receiver 1202.

[00141] In yet another implementation, as shown in FIG. 12B, the setscrew 1107 can be tightened to effect locking of two arms 1103, wherein the first arm 1103 includes a substantially cylindrical collet-type receiver end 1201 and the second arm 1103 (not shown) includes a receiver end 1112 configured to interconnect within the collet-type receiver end 1201. In this implementation, tightening the setscrew 1107 creates a load that compresses the substantially cylindrical collet-type receiver end 1201 of the first arm 1103 against the receiver 1202 (see FIG. 12B), thereby deflecting one or more deformable fingers 1204 (not shown) around the receiver end 1112 of the second arm 1103 to effect locking of both arms 1103 into a position.

[00142] In a further implementation, as shown in FIG. 12C and 12D, the setscrew 1107 can be tightened to effect locking of two arms 1103, wherein the first arm 1103 includes a substantially spherical collet-type receiver end 1201 and the second arm 1103 includes a receiver end 1112 configured to interconnect within the collet-type receiver end 1201. In this implementation, tightening the setscrew 1107 creates a load that compresses the substantially spherical collet-type receiver end 1201 of the first arm 1103 against the receiver 1202, thereby deflecting one or more deformable fingers 1204 around the receiver end 1112 of the second arm 1103 to effect locking of both arms 1103 into a position (see FIG. 12C).

[00143] In another implementation, shown in FIGS. 11D, 12B and 12D, the setscrew 1107 includes a setscrew aperture 1115. The setscrew aperture 1115 can be configured to substantially align with the longitudinal aperture 1106 of the base 1102, thereby enabling through passage between the longitudinal aperture 1106 of the arm 1103 and base 1102 (as discussed above).

[00144] As shown in FIGS. 11A-11D, and 13A-13B, the one or more arms 1103 of the screw assembly 1101, include a body 1111 wherein the body 1111 has an elongate

shape and includes a connector end 1108 for attachment to a support structure 1109, and a receiver end 1112. In one implementation, the elongate shape of the body 1111 of the arm 1103 is a rod. In another implementation, the elongate shape of the body 1111 of the arm 1103 is substantially a longitudinally split rod. In another implementation, the elongate shape of the body 1111 of the arm 1103 is a shape configured for fitted interrelation between two or more arms 1103 positioned in a first position that is substantially parallel to a long axis of the base 1102 (not shown). For example, the fitted interrelation can be comprised of a longitudinally split rod shape.

[00145] In another implementation, as shown in FIGS. 11C-11E and 13A-13B, the elongate shape of the body 1111 of the arm 1103 includes an offset section 1113. The offset section 1113 can be configured to provide a low-profile to the screw assembly 1101 when the one or more arms 1103 are positioned substantially parallel to a long axis of the base 1102 (See FIGS. 11D and 12B). Additionally, the offset section 1113 can provide a linear alignment of the base 1102 and the body 1111 of the arm 1103 when the arm 1103 is positioned substantially parallel to a long axis of the base 1102 (See FIGS. 11D and 12B).

[00146] In another implementation, as shown in FIGS. 11D, 12B and 12D, the body 1111 of the arm 1103 includes a longitudinal aperture 1106. In one implementation, the longitudinal aperture 1106 is a channel or groove running the length of the body 1111 of the arm 1103 (not shown). In a further implementation, two interrelating arms 1103 can have longitudinal apertures 106 that align to form a single longitudinal aperture 1106 when the arms 1103 are interrelated. The longitudinal aperture 1106 of the body 1111 of the arm 1103 can be coaxially aligned with the longitudinal aperture 1106 of the base 1102 of the screw assembly 1101. The longitudinal aperture 1106 traverses the length of the screw assembly 1101, and provides an aperture for the passage of instruments, tools, and guides (e.g. a K-wire)

[00147] The receiver ends 1112 of the one or more arms 1103 can include a hinge means for hinged interconnection with the base head 1104 e.g., as shown in FIGS. 11A-11B. In such an implementation, a locking means can be provided whereby after deployment, the one or more arms 1103 are lockable into a position substantially perpendicular to the long axis of the base 1102. An example of such a locking means can be a one-way ratchet configuration (not shown).

**[00148]** In another implementation, the receiver end 1112 of a single arm 1103 can be cylindrical shape for interconnection within the receiver 1202 of the base head 1104. In such an implementation the receiver 1202 can be an aperture in which the receiver end 1112 of the arm 1103 is received.

**[00149]** In another implementation, the receiver ends 1112 of two arms 1103 can be interconnecting and disposed within the base head 1104. For example, the receiver ends 1112 can interconnect by way of a collet-type design. In a first example, the two interconnecting receiver ends 1112 can have a cylindrical-shaped collet-type design including: a first collet-type receiver end 1201 having a substantially cylindrical recess, one or more relief cuts 1203 and one or more deformable fingers 1204, and; a second solid cylindrical-shaped receiver end 1112 configured for fitting into the cylindrical recess of the collet-type receiver end 1201 (not shown).

**[00150]** In a second example, as shown in FIGS. 11A, 11B, 12C and 12D, the two interconnecting receiver ends 1112 can have a spherical-shaped collet-type design including: a first collet-type receiver end 1201 having a substantially spherical recess, one or more relief cuts 1203 and one or more deformable fingers 1204, and; a second solid spherical-shaped receiver end 1112 configured for fitting into the first collet-type receiver end 1201.

**[00151]** Additionally, as shown in FIGS. 12A and 12B, which illustrate a cylindrical shaped collet-type design, and FIGS. 12C and 12D, which illustrate a spherical-shaped collet-type design, the respective receiver ends 1112 can include a longitudinal aperture 1106 passing through the interconnected receiver ends 1112. Such a longitudinal aperture 1106 can be configured to provide coaxial alignment with the longitudinal aperture 1106 of the base 1102, when the arms 1103 are positioned substantially parallel to the long axis of the base 1102 (see FIGS. 12B and 12D).

**[00152]** As shown in FIGS. 11A-11D, 13A and 13B, the connector ends 1108 of the one or more arms 1103 are configured for attachment to a support structure 1109. As shown in FIGS. 13A and 13B, one or more support structures 1109 can be attached to a screw assembly 1101 to provide a support assembly 1301. In one implementation, each support structure 1109 is comprised of an anchor 1105, an aperture 1110, and a locking means (see FIGS. 13A and 13B). The one or more support structures 1109 can be made

of materials that are durable and that can be implanted in a body, including titanium, stainless steel, carbon fiber, etc. In one implementation, the one or more support structures 1109 are made of titanium. In another implementation the one or more support structures 1109 are made of a biocompatible material, a reabsorbable material, or a combination of any of the foregoing materials.

[00153] In one implementation, each support structure 1109 is configured for attachment to a structure in a patient (e.g. bone). As shown in FIGS. 13A and 13B, the locking means for the one or more support structures 1109 can be a setscrew 1107. Alternatively, the locking means can be a cam (not shown).

[00154] As shown in FIG. 14, two support structures 1109 can be attached to a screw assembly 1101 to provide a support assembly 1301 that can be implanted into the pedicles 1403 of vertebra 1402 in a spine 1401 to effect support of the spine 1401. In another implementation, a single support structure 1109 can be attached to a screw assembly 1101 to provide a support assembly 1301 that can be implanted into the pedicles 1403 of vertebra 1402 in a spine 1401 to effect support of the spine 1401.

[00155] Referring to FIGS. 13A, 13B and 14, a method of using the invention to support the spine 1401 includes the steps of: 1) delivering to bone a screw assembly 1101 having one or more arms 1103, a base 1102 and an interconnection means (e.g. a base head receiver 1202 interconnected with the receiver end 1112 of one or more arms 1103); 2) delivering to flanking bone, one or more support structures 1109 having apertures 1110 and locking means for the connector ends 1108 of the arms 1103 of the screw assemblies 101; 3) deploying the one or more arms 1103 of the screw assembly 1101 to the flanking support structures 1109; 4) locking the one or more arms 1103 of the screw assembly 1101 in a desired position; and 5) engaging the locking means of the support structure 1109 apertures 1110. In one implementation, the one or more flanking support structures 1109 can be delivered, for example, to bone including one or more vertebral bodies on one or both sides of a vertebral body to which the screw assembly 1101 is delivered. In another implementation, the one or more flanking support structures 1109 are delivered to vertebral bodies adjacent to the vertebral body to which the screw assembly 1101 is delivered. In another implementation, one or more of the flanking support structures 1109 are delivered to vertebral bodies distal to the adjacent-most vertebral body.

**[00156]** The method of supporting the spine can also be used in conjunction with a kyphoplasty procedure. Kyphoplasty is a percutaneous technique involving the use of an expandable structure, such as a balloon catheter, to create a cavity or void within the vertebral body, followed by filling the cavity with a bone substitute to form an "internal cast". The bone substitute could be any appropriate filling materials used in orthopedic surgery, including but not limited to, allograft or autograft tissue, hydroxyapatite, epoxy, PMMA bone cement or synthetic bone substitutes, medical grade plaster of Paris or calcium phosphate or calcium sulfate cements. Methods and instruments suitable for such treatment are more fully described in U.S. Pat. Nos. 4,969,888 and 5,108,404. Kyphoplasty can be used to reduce vertebral compression fractures and to move bone with precision, thus restoring as close to normal the pre-fracture anatomy of the vertebral body. Vertebral compression fractures caused by trauma (for example, due to automobile accidents or falls) have traditionally been treated with open reduction, internal fixation stabilization hardware and fusion techniques using a posterior approach. The stabilization hardware is used to offload the fractured vertebral body and to stop motion across the disk so that bone graft can fuse one vertebral body to the next and the stabilization hardware usually becomes a permanent implant. In trauma, the stabilization hardware may be designed to facilitate easy removal after fusion has occurred. Stabilization hardware can take many forms, including those described herein.

**[00157]** The combination of kyphoplasty and insertion of stabilization hardware utilizing the naturally occurring interior muscle plane as described in Wiltse and Spencer, Spine (1988) 13(6):696-706, satisfies the goals of improving the quality of patient care through minimally invasive surgical therapy.

**[00158]** A number of preferred embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. For example, while the some implementations have been described using screws to anchor into bony structures, the scope of the invention is not so limited. Any means of anchoring can be used, such as a cam, screw, staple, nail, pin, or hook. Accordingly, other embodiments are within the scope of the following claims.

**WHAT IS CLAIMED IS:**

1. An apparatus comprising:

a screw assembly configured for supporting a structure, the screw assembly including

a base,

5 an arm, and

an interconnection means for coupling the base to the arm, the interconnection means allowing the arm to be positionable in a first position that is parallel to a long axis of the base and positionable in a second position that is perpendicular to the long axis of the base,

10 the base configured for attachment to a structure in a patient.

2. The apparatus of claim 1, wherein the arm is a support configured for receiving one or more anchor assemblies including a means for locking the anchor assembly to the support, the support including a top portion and a bottom portion.

15

3. The apparatus of claim 1, wherein the base is comprised of a base head having a shape and a locking means, and an anchor.

4. The apparatus of claim 3, wherein the anchor is selected from the group  
20 consisting of a screw, staple, nail, hook and a pin.

5. The apparatus of claim 2, wherein the support is comprised of a connector end,

one or more apertures, and

25 a receiver.

6. The apparatus of claim 5, wherein the connector end is configured for interconnection of the support and the base of the screw assembly.

30 7. The apparatus of claim 5, wherein the connector end is configured for hinge-type interconnection of the support and the base of the screw assembly.

8. The apparatus of claim 5, wherein the one or more apertures of the support include a first connector end proximal aperture having a dimensional configuration to support a range of movement of the base in relation to the support, and, one or more second connector end distal apertures providing access to the base and the  
5 means for locking the anchor assembly to the support, when assembled with the support.

9. The apparatus of claim 1, wherein the support is comprised of a support member having a top portion and a bottom portion, a head assembly, and  
10 an interconnection means.

10. The apparatus of claim 9, wherein the support member is comprised of a receiver, and  
one or more apertures.

11. The apparatus of claim 10, wherein the one or more apertures include a first aperture wherein an anchor assembly is passable therethrough and lockably engagable with the support member, and  
a second aperture wherein access is provided from the top portion of the support  
20 member to access the head assembly.

12. The apparatus of claim 9, wherein the head assembly is comprised of a connector end,  
an aperture having a dimensional configuration supporting a range of movement  
25 of the base in relation to the support, and  
a connector end proximal aperture having a dimensional configuration to support a range of movement of the base in relation to the support, and  
a locking means for securing the head assembly to the support member,  
wherein the head assembly is configured for interconnection with the support member.

13. The apparatus of claim 1, wherein the arm is configured for attachment to a support structure.

14. The apparatus of claim 13, wherein the structure in a patient is bone.

15. The apparatus of claim 13, further comprising a support structure and wherein the screw assembly is attached to the support structure by the arm.

5

16. The apparatus of claim 15, further comprising two screw assemblies wherein the two screw assemblies are attached to the support structure.

10 17. The apparatus of claim 13, wherein the screw assembly has an overall length sized for subcutaneous support of a posterior of a spine.

18. The apparatus of claim 13, wherein the arm is comprised of a body, a base yoke and a connector end.

15 19. The apparatus of claim 18, wherein the body of the arm is rod shaped.

20. The apparatus of claim 13, wherein the base is comprised of a base head and an anchor.

20 21. The apparatus of claim 20, wherein the anchor is selected from the group consisting of a screw, staple, hook and a nail.

22. The apparatus of claim 13, wherein the interconnection means includes a press-fit cross pin.

25

23. The apparatus of claim 13, wherein the interconnection means is comprised of an open saddle head and coupling-cross piece.

24. The apparatus of claim 13, further comprising:  
30 a support structure including  
an anchor,  
a receiver, and  
a locking means;



wherein the anchor is configured for attachment to a structure in a patient;  
wherein the receiver includes  
a receiver having an opening for attachment to the arm of the screw assembly; and  
wherein the locking means is configured to lock the arm to the support structure,  
5 after the support structure has been deployed in a patient.

25. The apparatus of claim 1, wherein the screw assembly includes two or more  
arms.

10 26. The apparatus of claim 25, wherein the interconnection means is selected  
from the list consisting of a hinge, a pin and a collet.

27. The apparatus of claim 25, wherein the base is comprised of a base head and  
an anchor.

15

28. The apparatus of claim 27, wherein the interconnection means is comprised of  
the base head and wherein the base head includes  
a receiver and a setscrew.

20 29. The apparatus of claim 28, wherein the setscrew secures the base to the two or  
more arms of the screw assembly.

30. The apparatus of claim 28, wherein tightening the setscrew effects locking of  
the two or more arms in a position in relation to the base.

25

31. The apparatus of claim 27, wherein the interconnection means is comprised of  
the base head and wherein the base head includes a hinge means.

30 32. The apparatus of claim 28, wherein the two or more arms are comprised of a  
body;  
wherein the body has an elongate shape and includes  
a connector end for attachment to a support structure, and

a receiver end for connection to the base head receiver portion of the interconnection means.

33. The apparatus of claim 32, wherein the elongate shape of the arm body  
5 includes an offset section;

wherein the offset section is configured to provide a linear alignment of the base and the arm body when the arm is positioned substantially parallel to a long axis of the base.

10 34. The apparatus of claim 32, wherein the elongate shape of the arm body is a shape configured for fitted interrelation between two or more arms positioned in a first position that is substantially parallel to a long axis of the base.

35. The apparatus of claim 32, wherein the receiver end of the two or more arms  
15 and the receiver portion of the base head include a hinge means.

36. The apparatus of claim 35, wherein a means is provided for locking the arm into a position substantially perpendicular to the long axis of the base.

20 37. The apparatus of claim 36, wherein the means provided for locking the arm is selected from the group consisting of a one-way ratchet, a setscrew and a cam.

38. The apparatus of claim 32, wherein the screw assembly includes two arms and the receiver ends of the two arms are configured for interconnection.

25 39. The apparatus of claim 38, wherein one of the receiver ends of the two arms includes

a first collet-type receiver end having a substantially cylindrical recess, and the other receiver end of the two arms includes

30 a substantially cylindrical shape for interconnection with the first collet-type receiver.

40. The apparatus of claim 36, wherein one of the receiver ends of the two arms includes

a first collet-type receiver end having a substantially spherical recess, and an other receiver end of the two arms includes

5 a substantially spherical shape for interconnection with the first collet-type receiver.

41. A method of supporting a bony structure, the method comprising the steps of:

- 10 1) delivering to bone a screw assembly comprising a support having a receiver, a base, an interconnection means, and a locking means;
- 2) deploying the support substantially perpendicular to the long axis of the base;
- 3) passing through the support and implanting one or more anchor assemblies having a base and a locking means into bone;
- 4) locking the bases within one or more of the anchor assemblies;
- 15 5) locking one or more of the anchor assemblies within the support receiver; and
- 6) engaging the locking means of the screw assembly to secure the position of the support in relation to the base.

42. A method of supporting the spine, the method comprising the steps of:

- 20 1) delivering to bone, two screw assemblies having arms, bases and interconnection means;
- 2) delivering to the vicinity of bone, a support structure having two receivers having locking means for the arms of the screw assemblies;
- 3) deploying the arms of the screw assemblies; and
- 25 4) engaging the locking means of the receivers to secure the arms of the screw assemblies to the support structure.

43. A method of supporting the spine, the method comprising the steps of:

- 30 1) delivering to bone a screw assembly having two or more arms, a base and an interconnections means;
- 2) delivery to flanking bone one or more support structures having an aperture and locking means for the arms of the screw assemblies;

- 3) deploying the two or more arms of the screw assembly to the flanking support structures;
- 4) locking the two or more arms of the screw assembly in a desired position; and
- 5) engaging the locking means of the support structure aperture.

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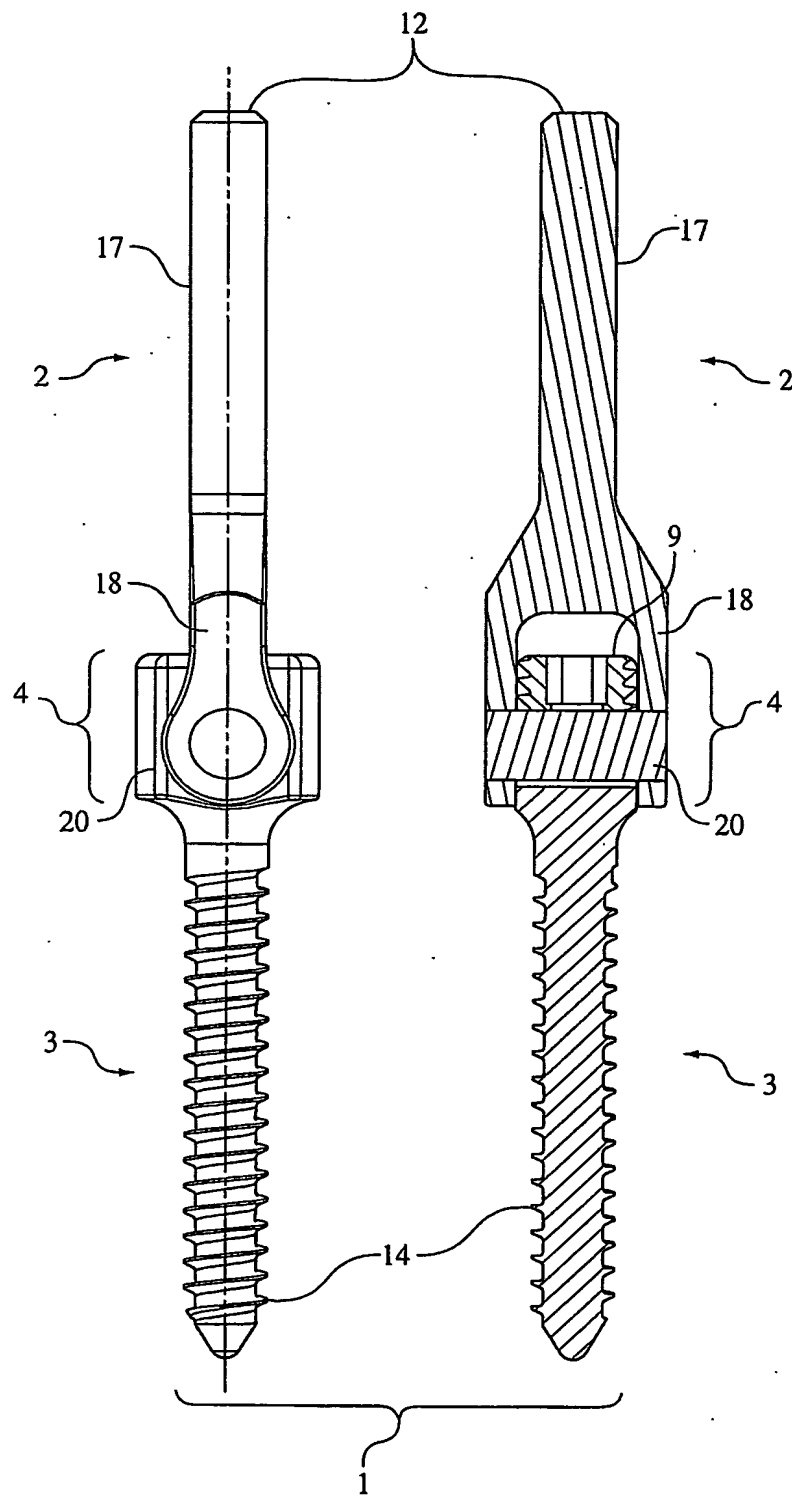


FIG. 1A

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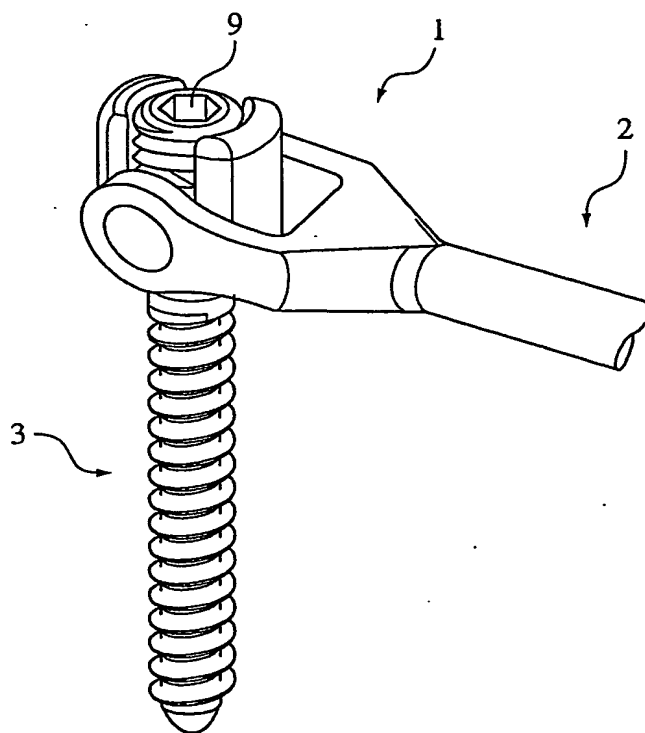
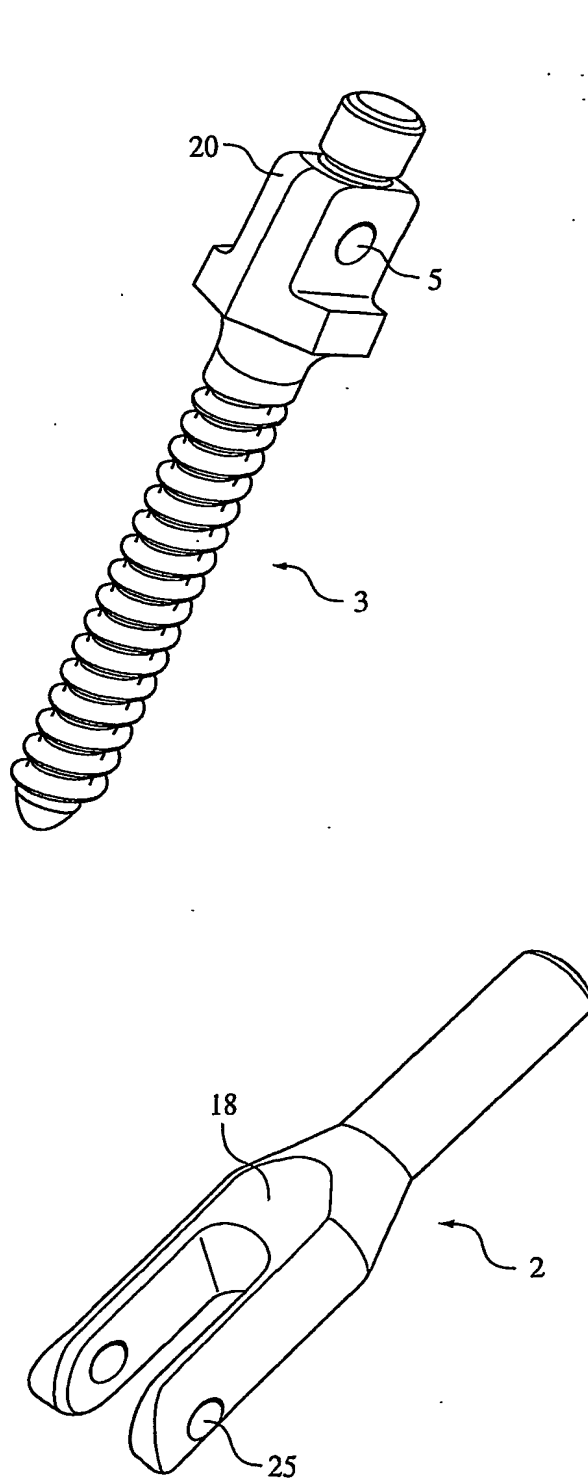


FIG. 1B

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FIG. 1C



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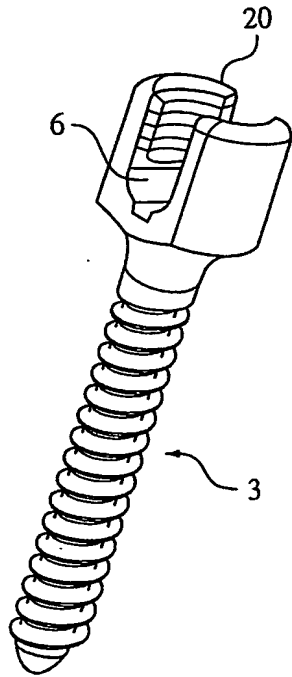


FIG. 1D

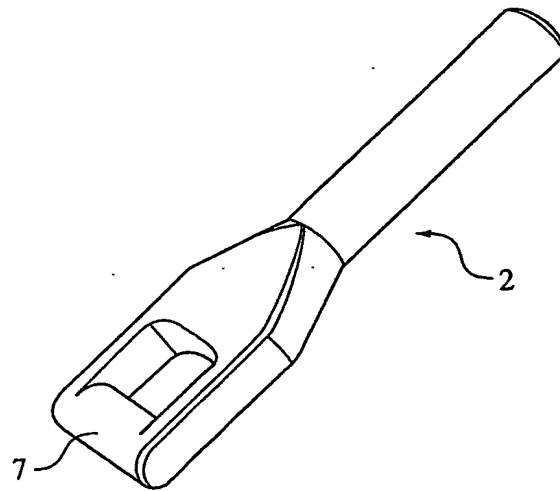


FIG. 1E

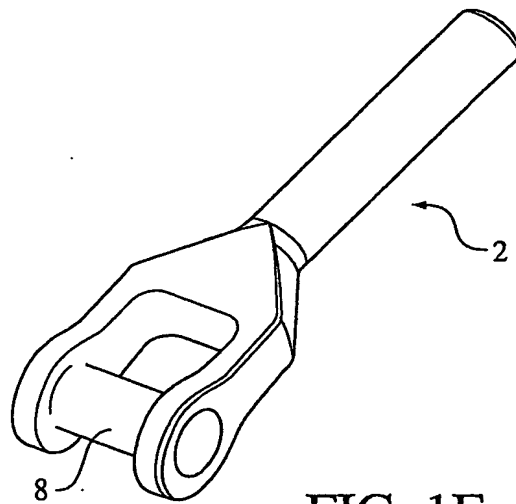


FIG. 1F



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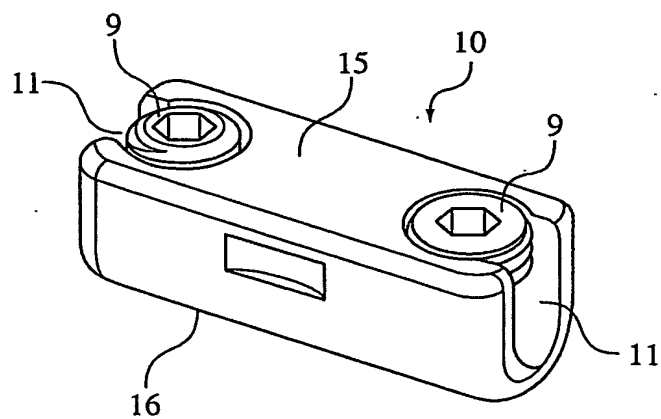


FIG. 2A

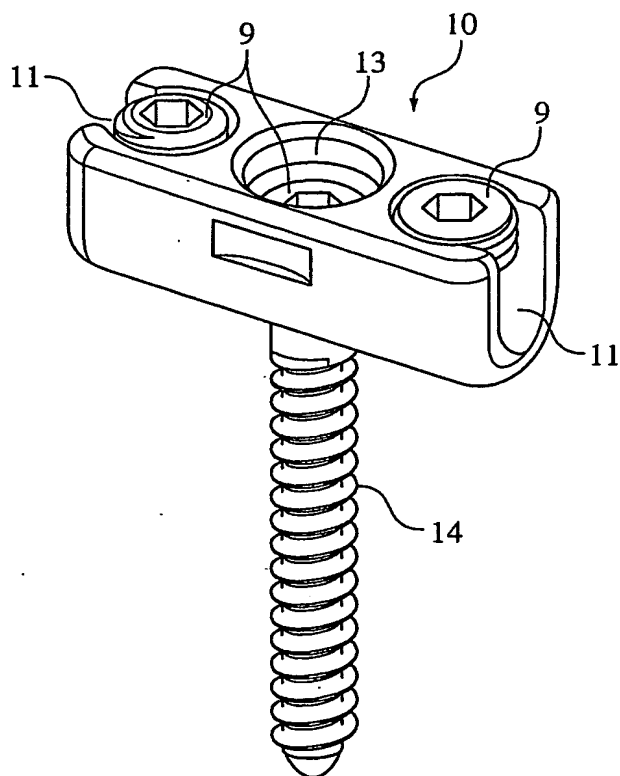


FIG. 2B

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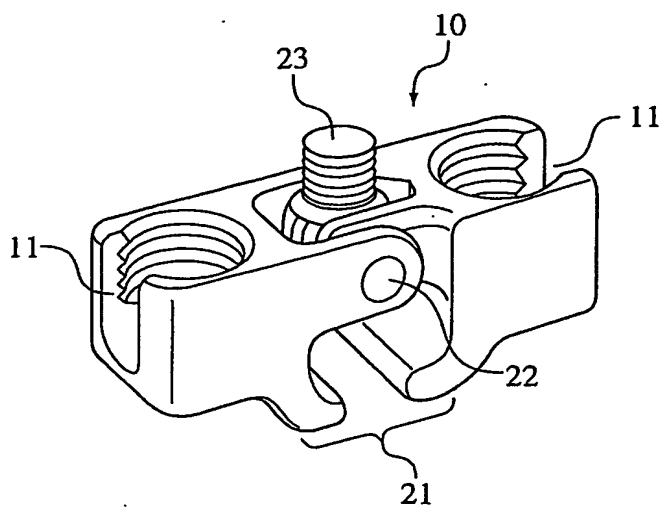


FIG. 2C

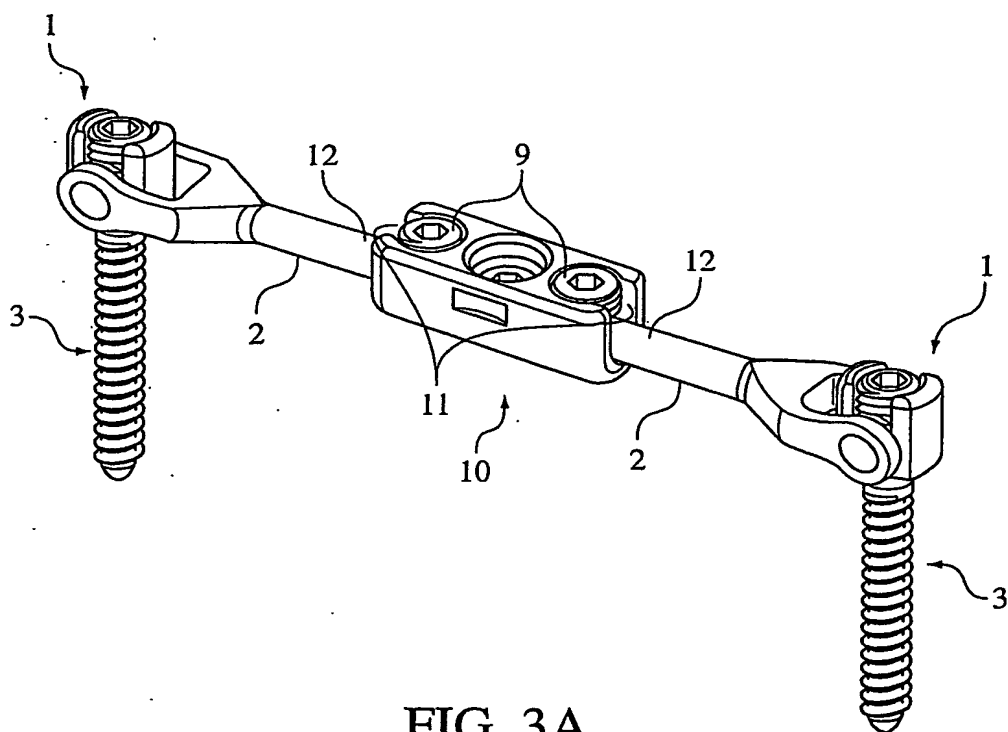


FIG. 3A

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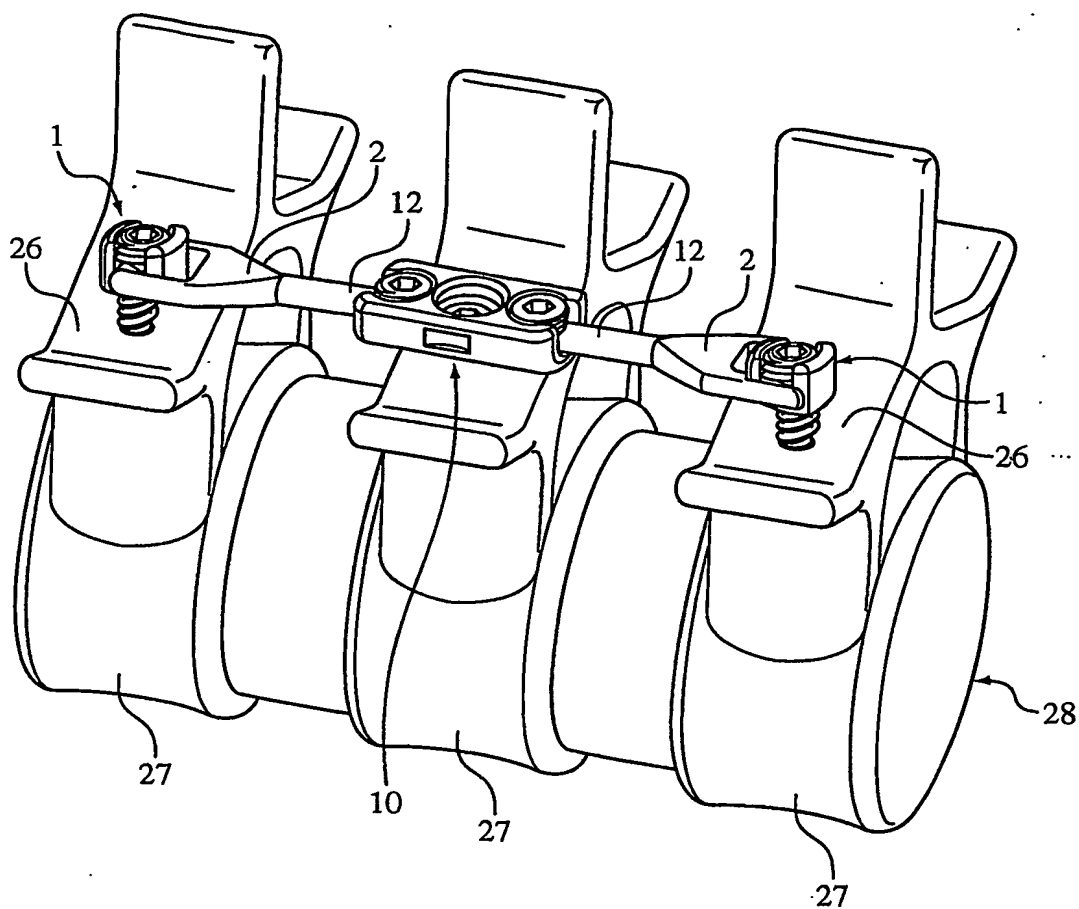


FIG. 3B

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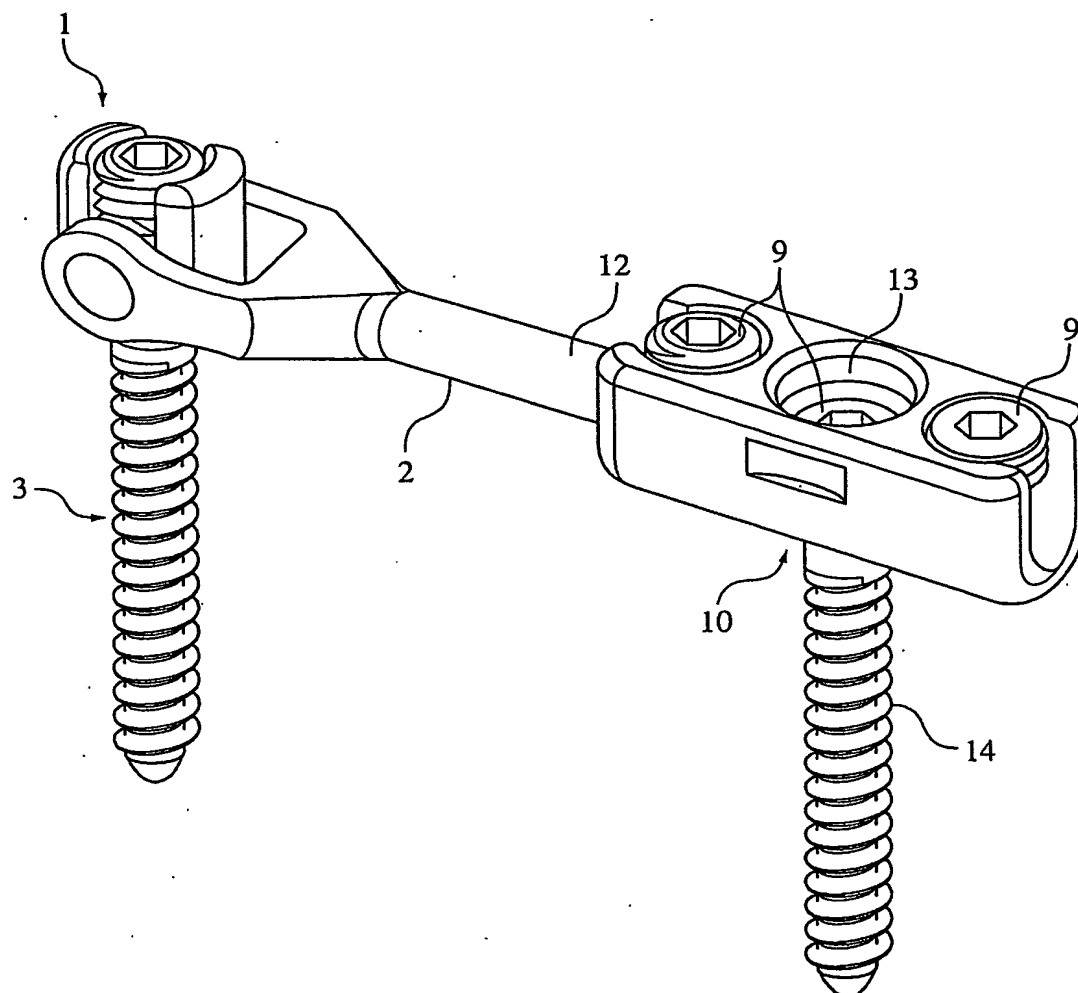


FIG. 4

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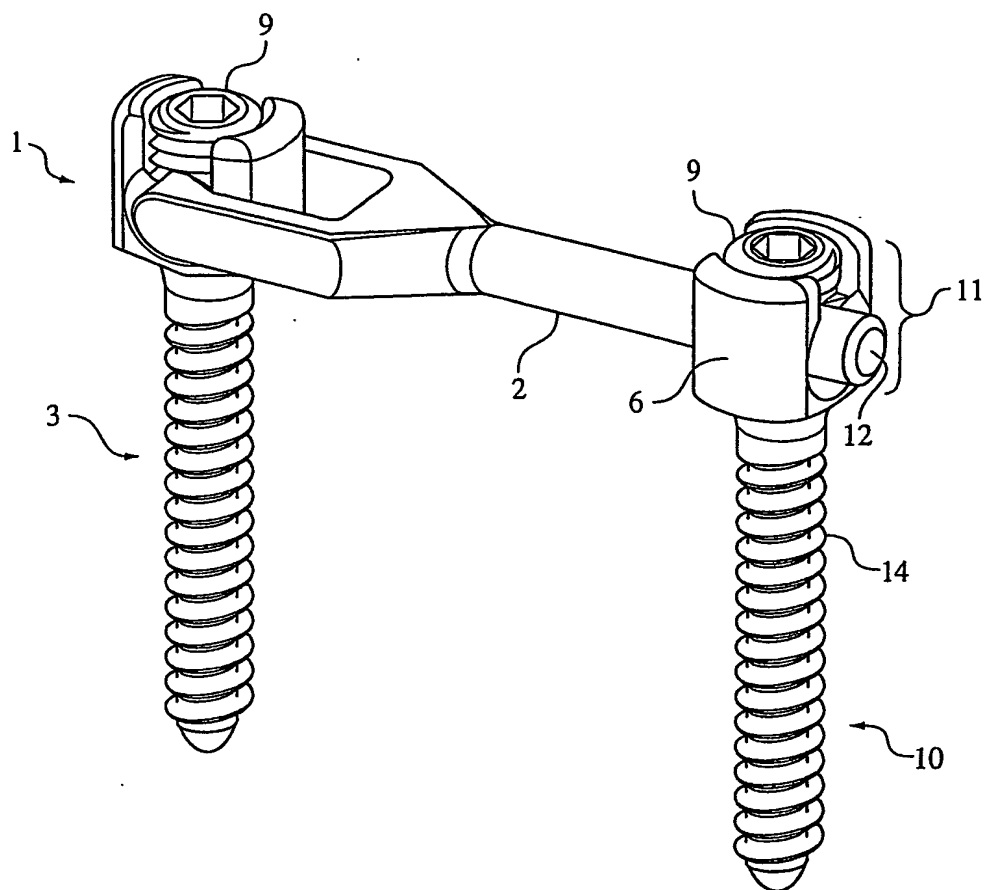


FIG. 5

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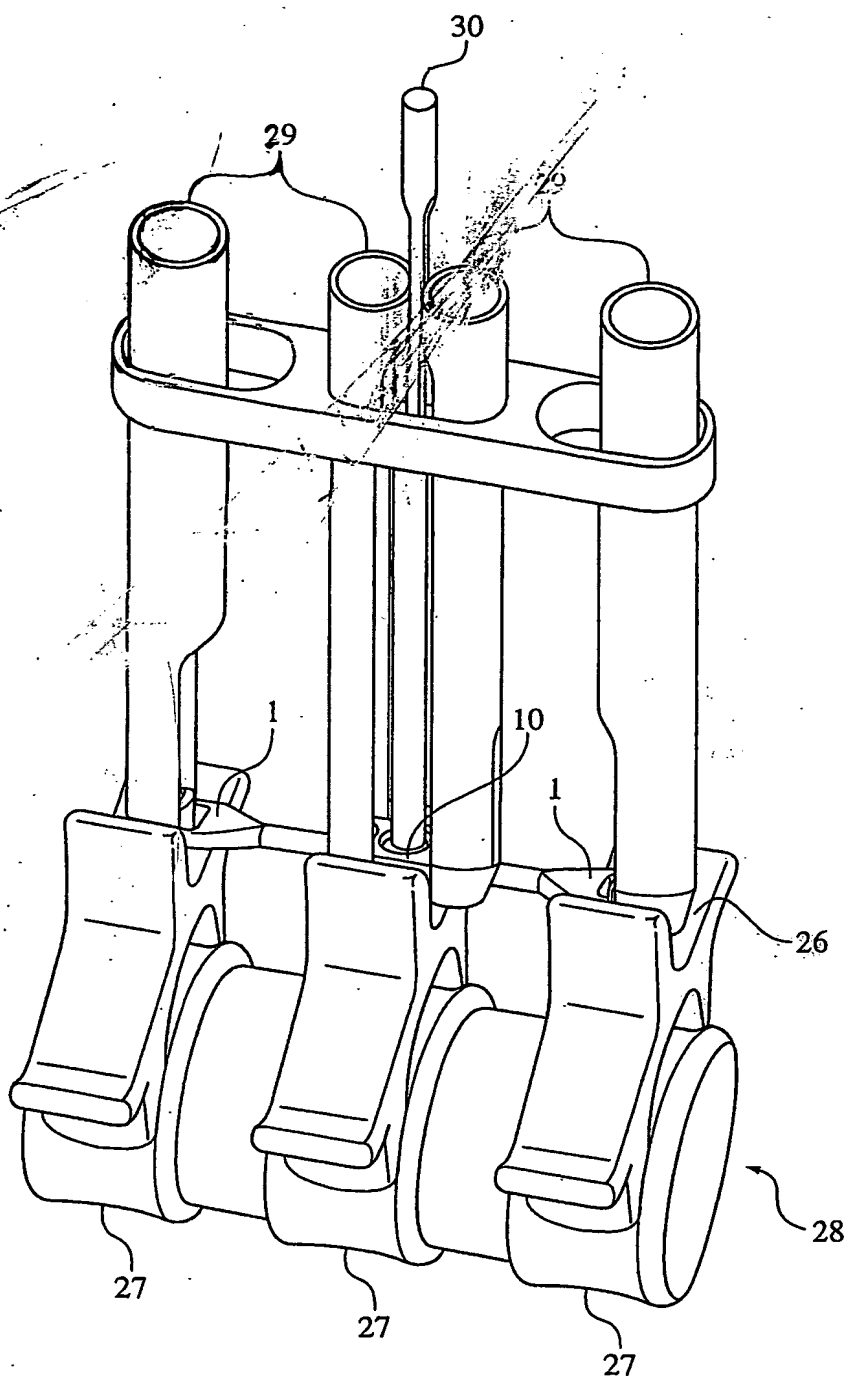


FIG. 6

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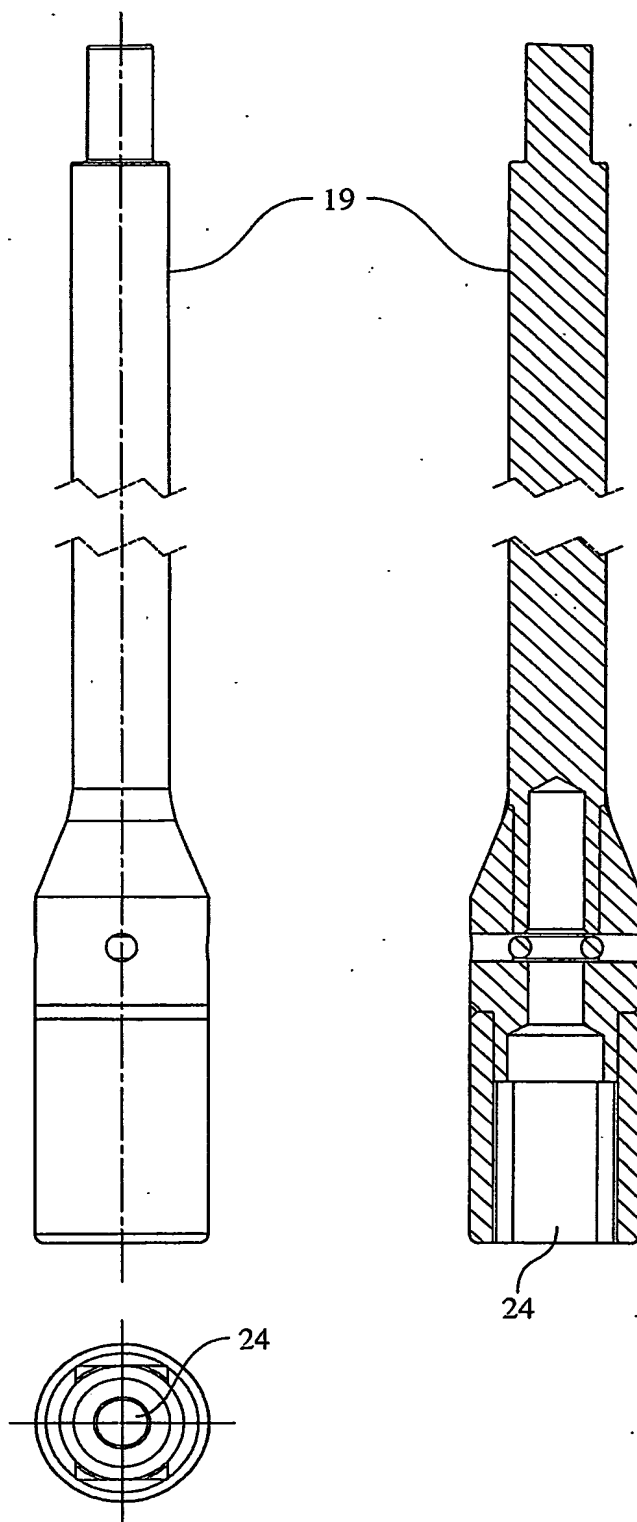


FIG. 7

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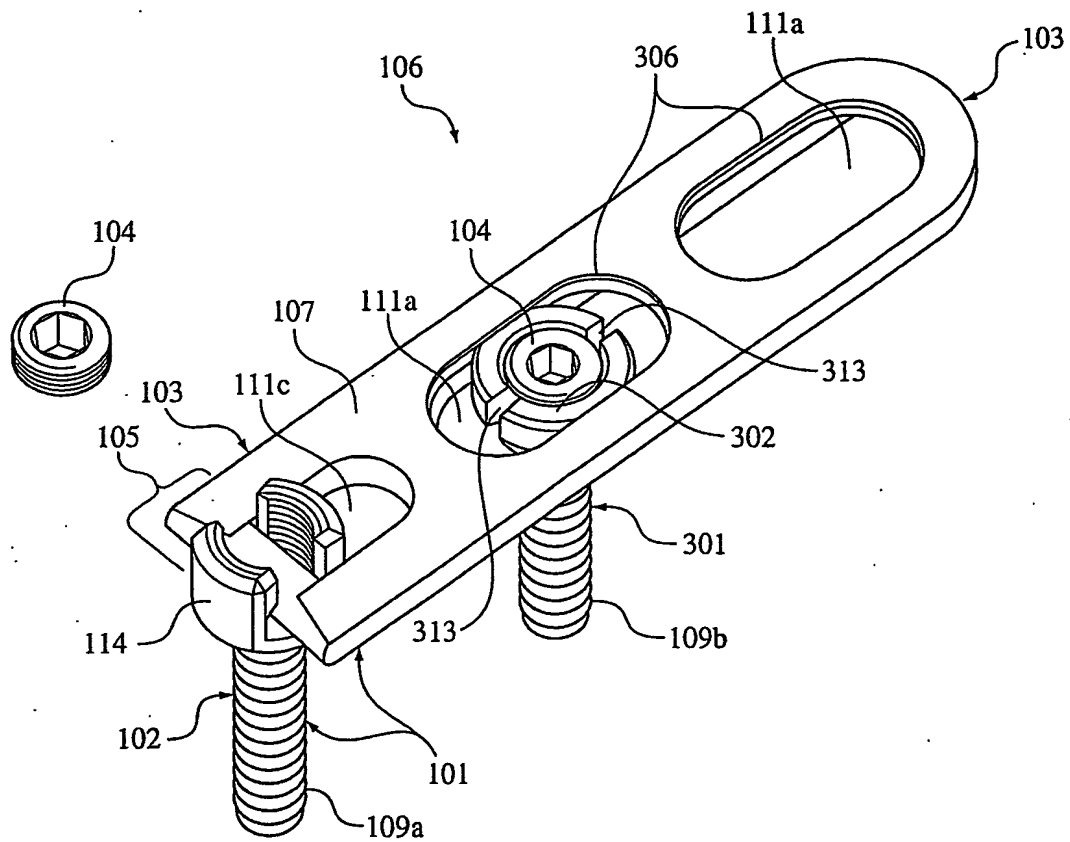


FIG. 8A



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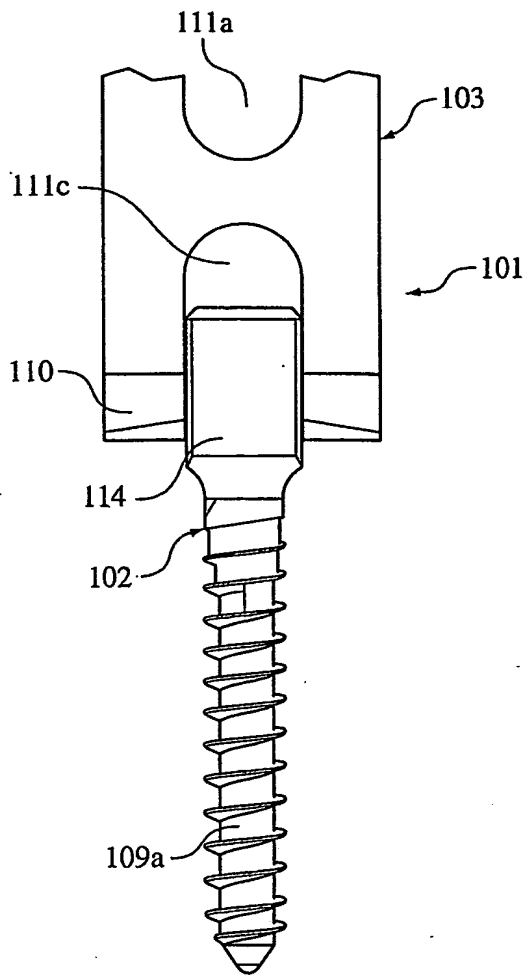


FIG. 8B

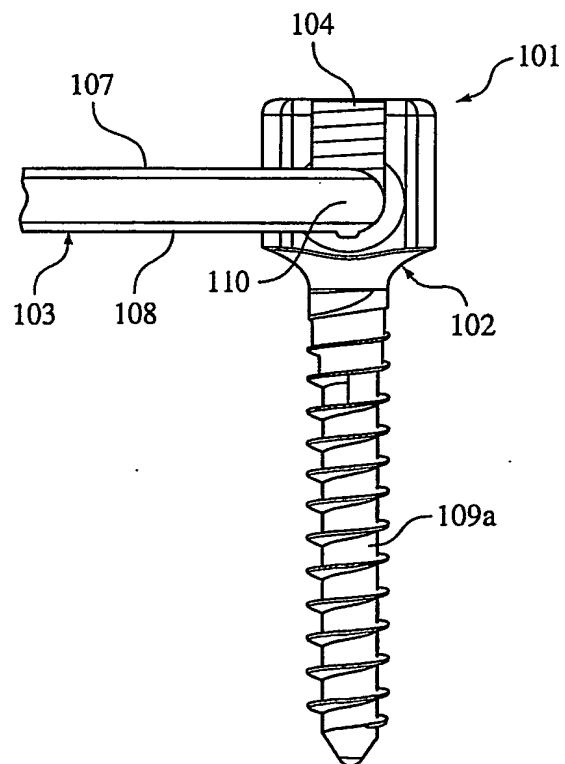


FIG. 8C

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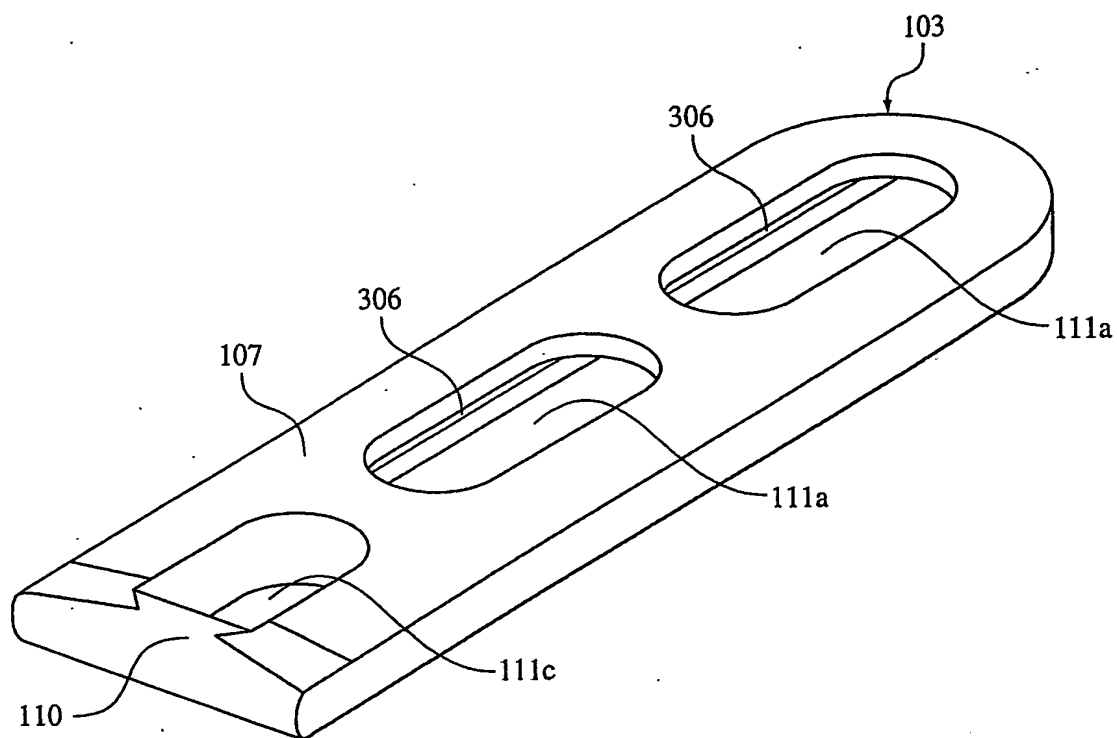
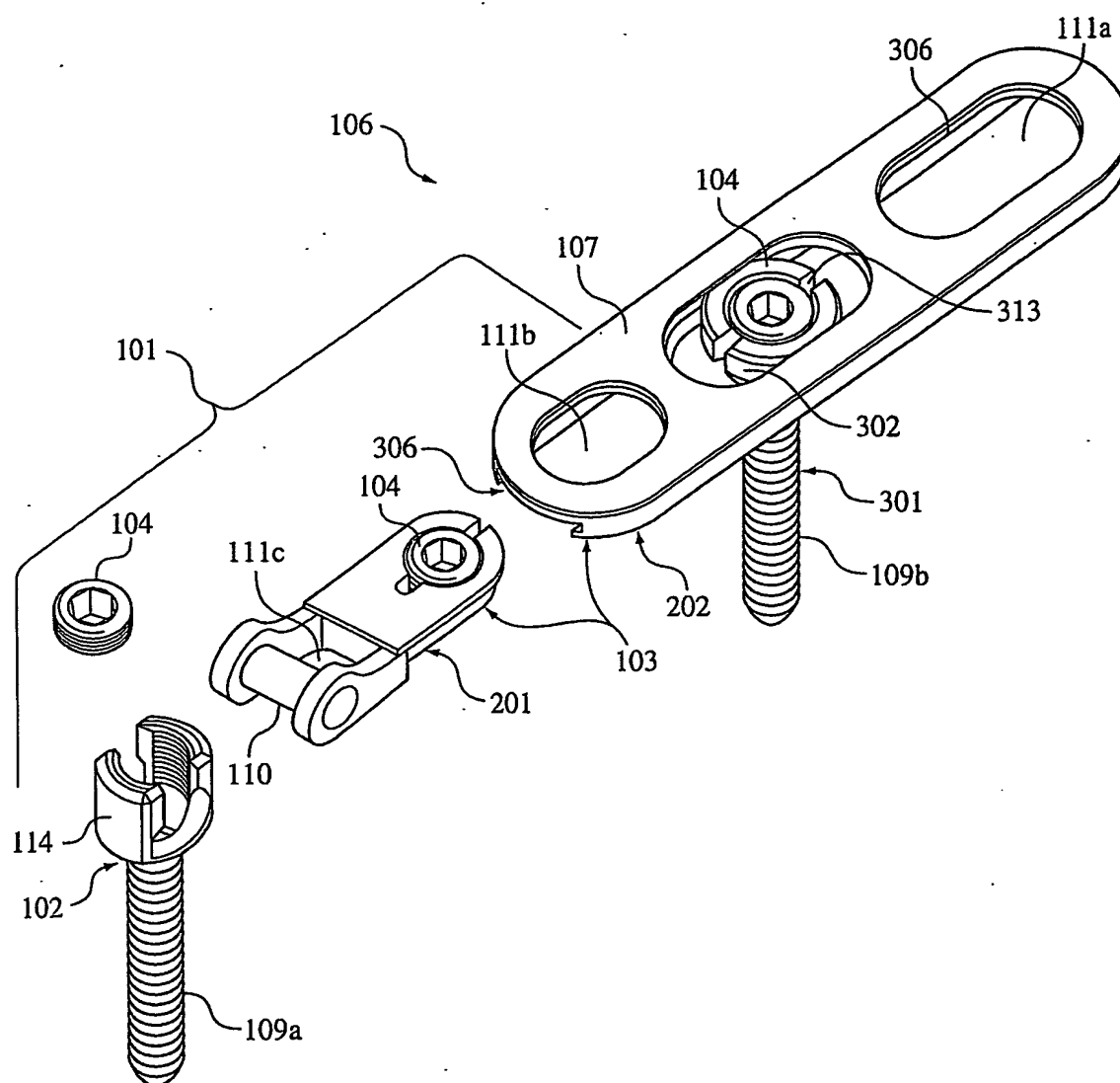


FIG. 8D

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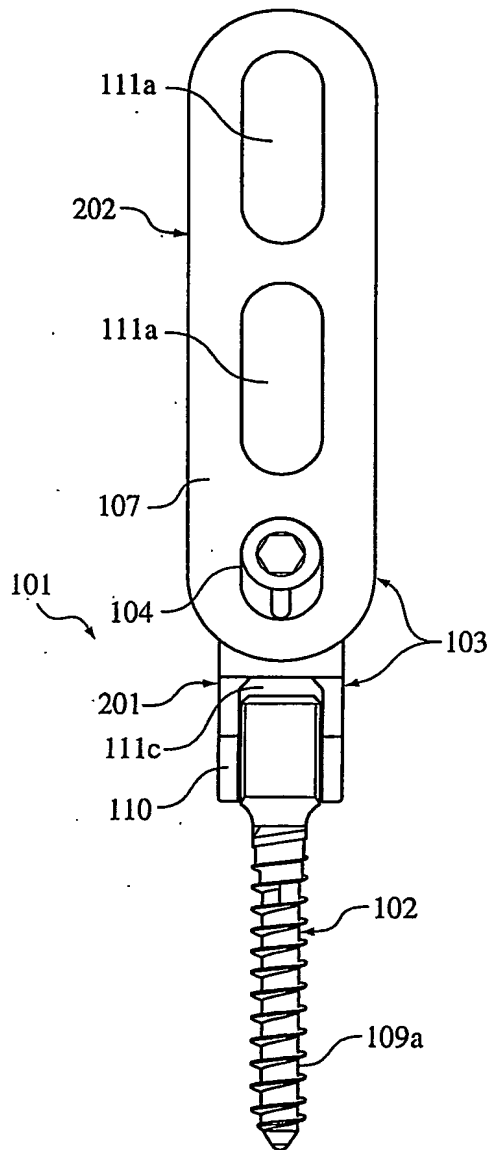


FIG. 9B

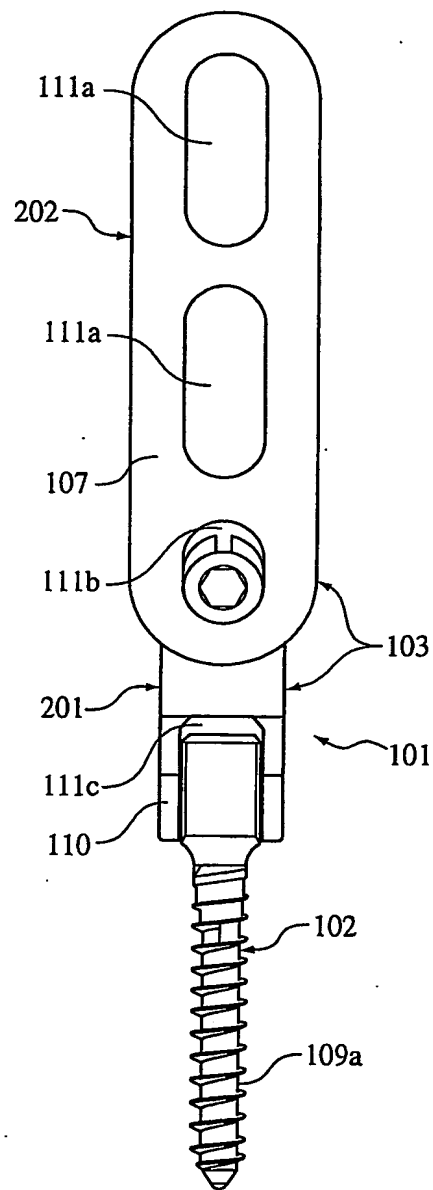


FIG. 9C

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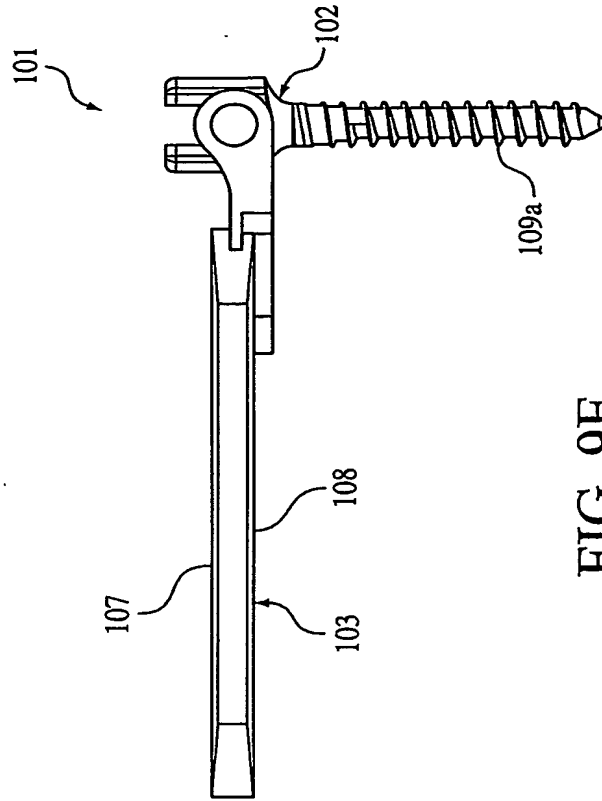


FIG. 9E

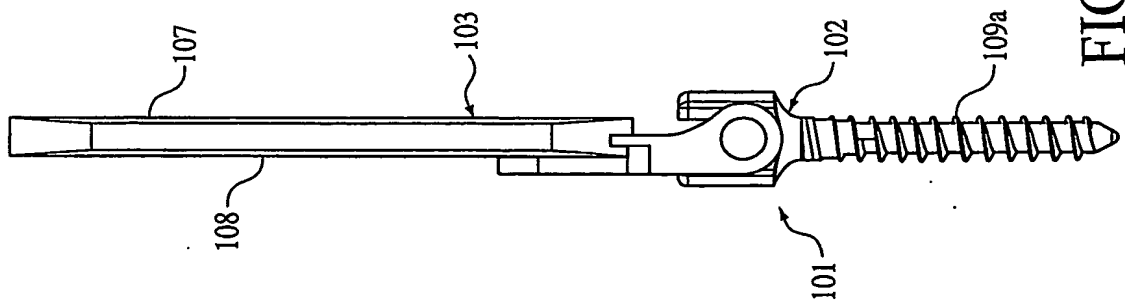


FIG. 9D

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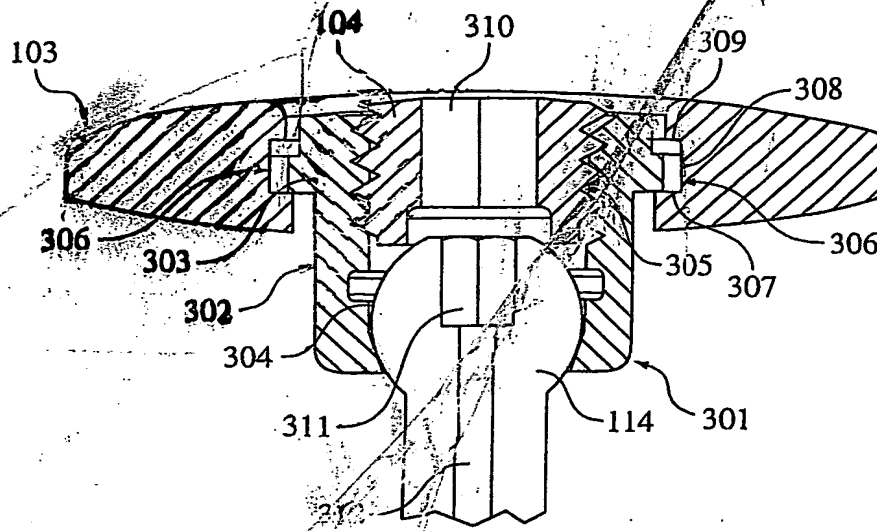


FIG. 10A

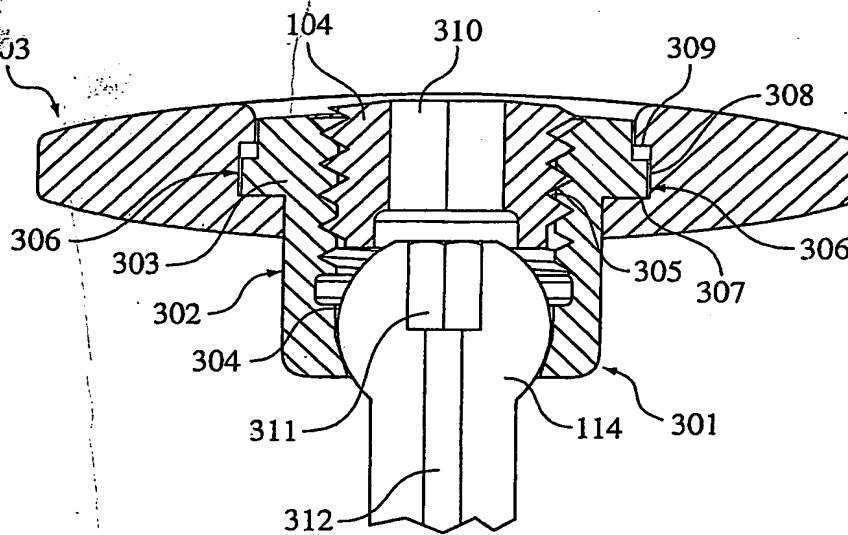


FIG. 10B

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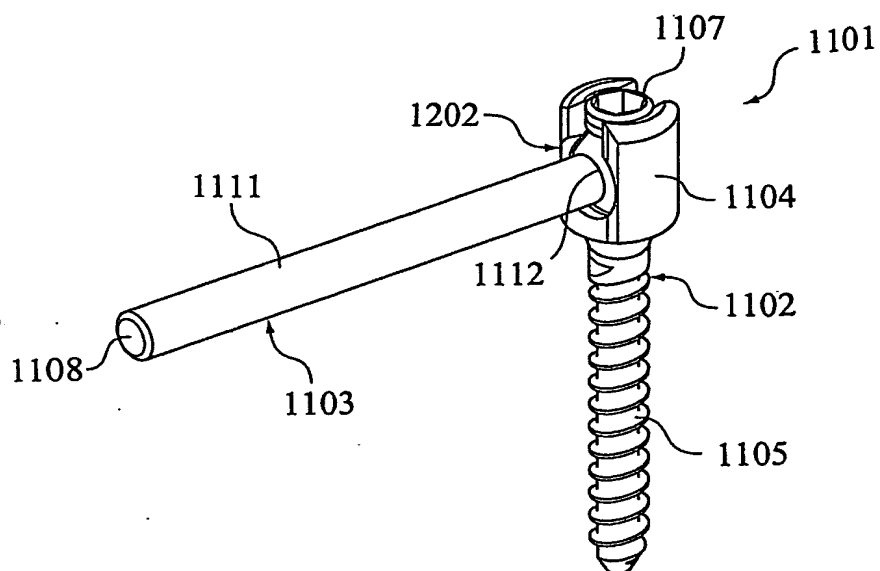


FIG. 11A

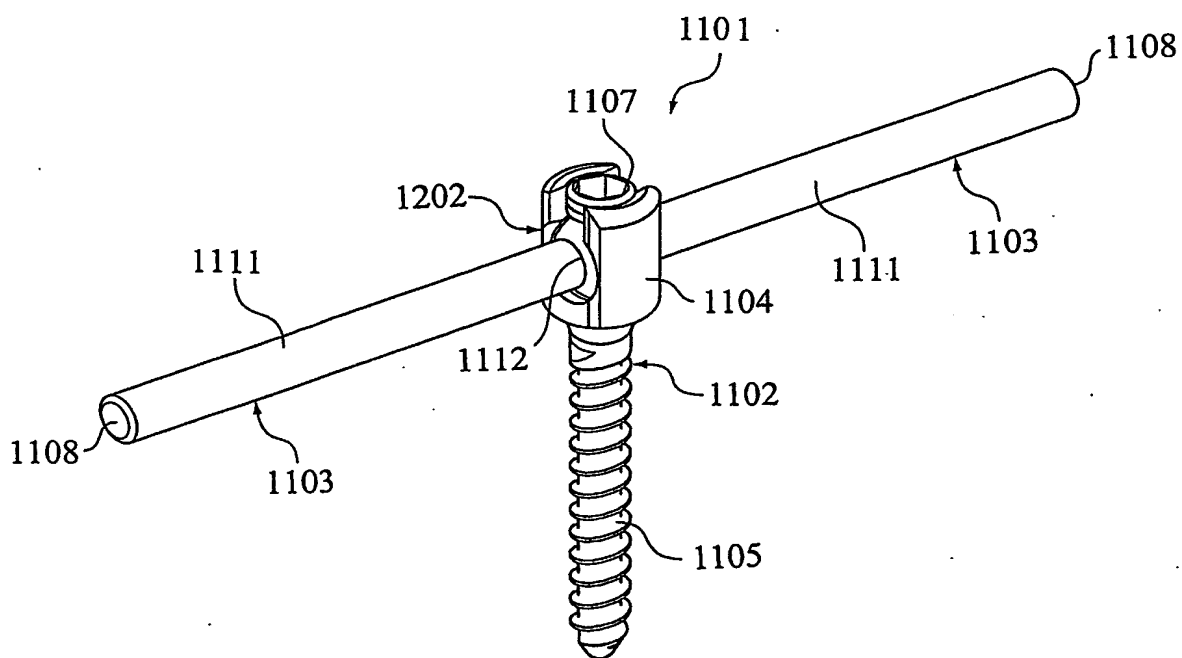


FIG. 11B

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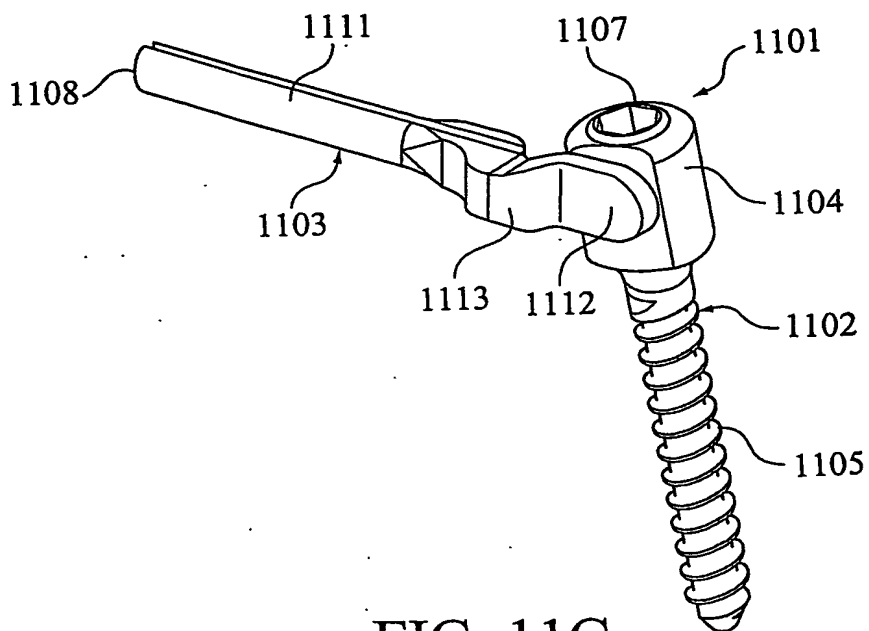


FIG. 11C

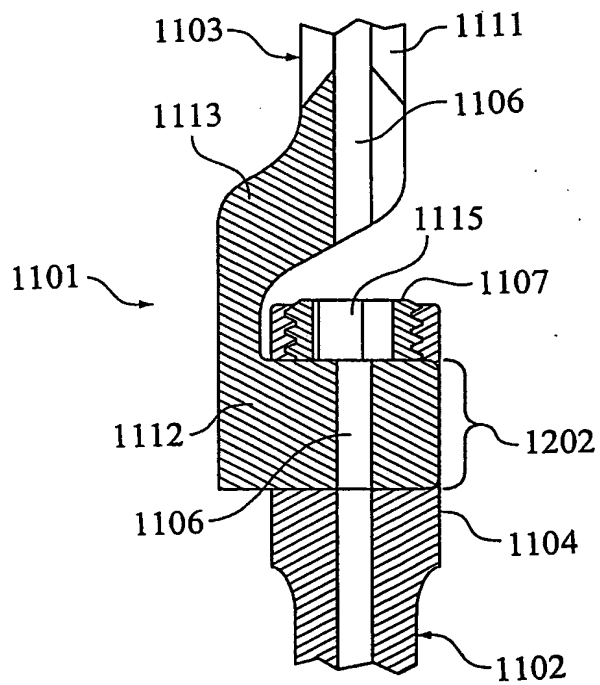


FIG. 11D



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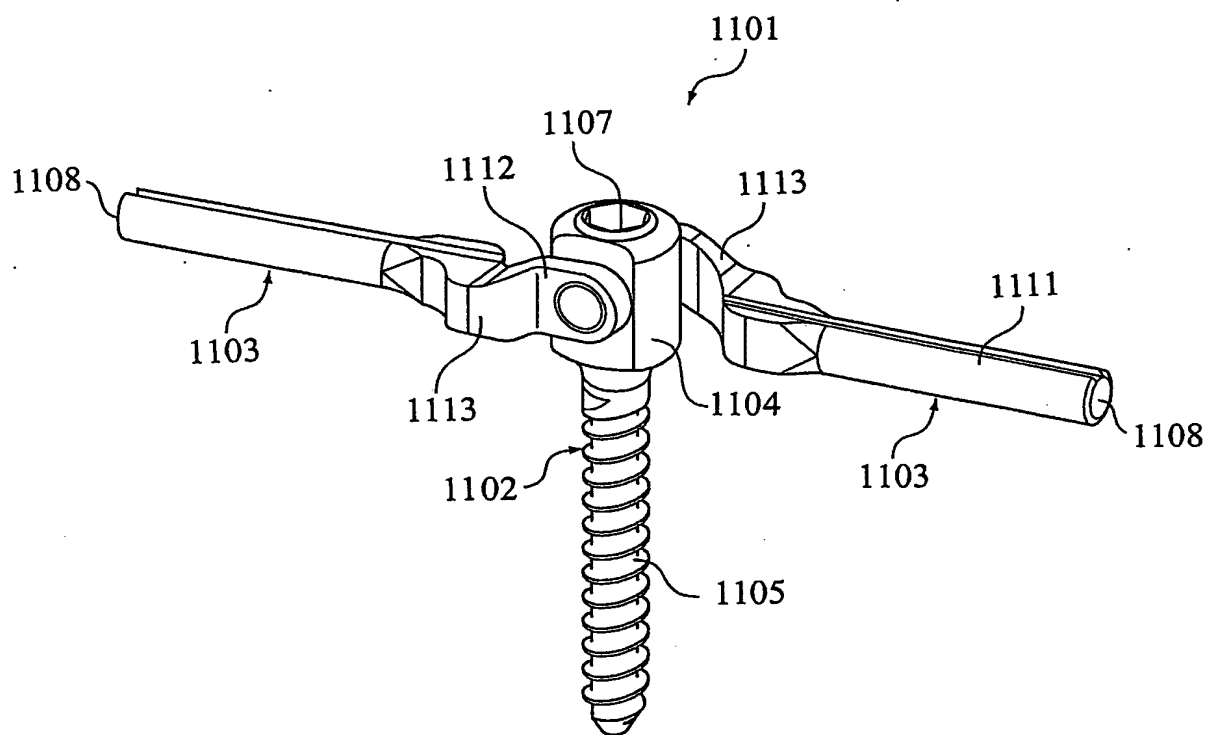


FIG. 11E

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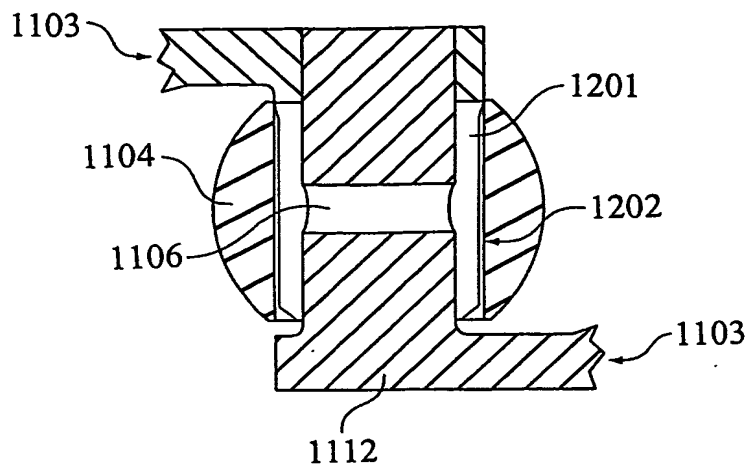


FIG. 12A

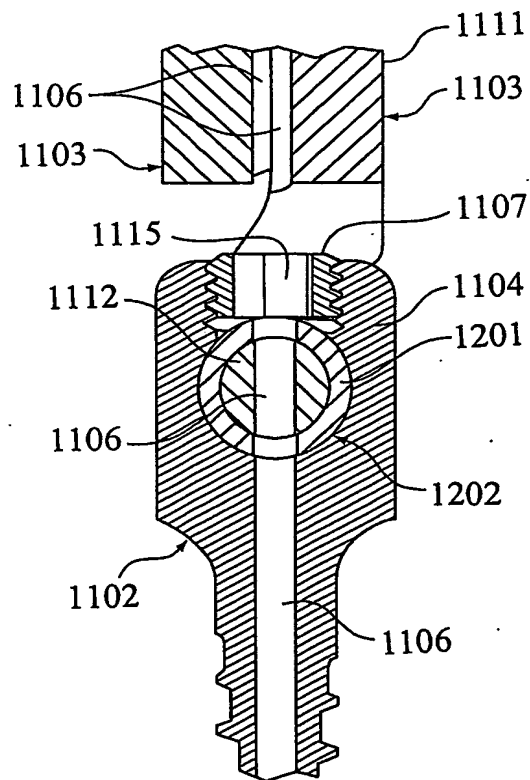


FIG. 12B

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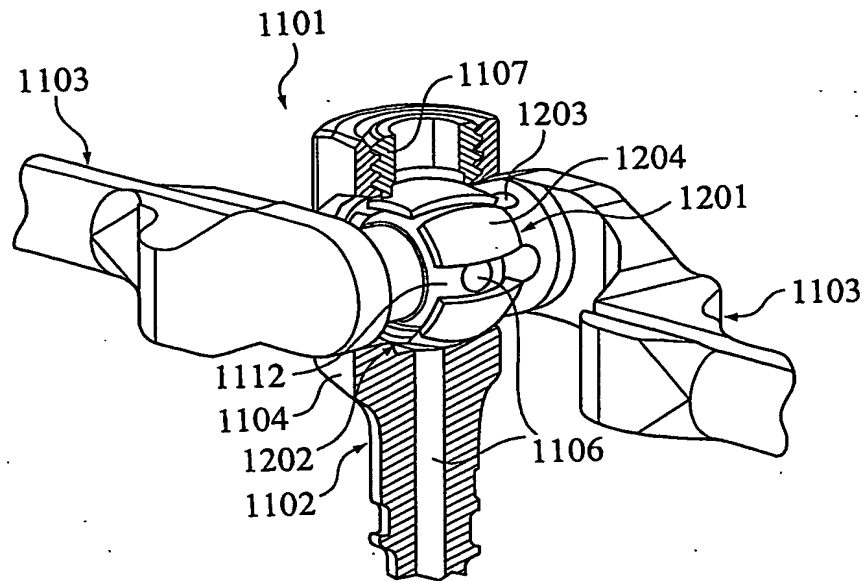


FIG. 12C

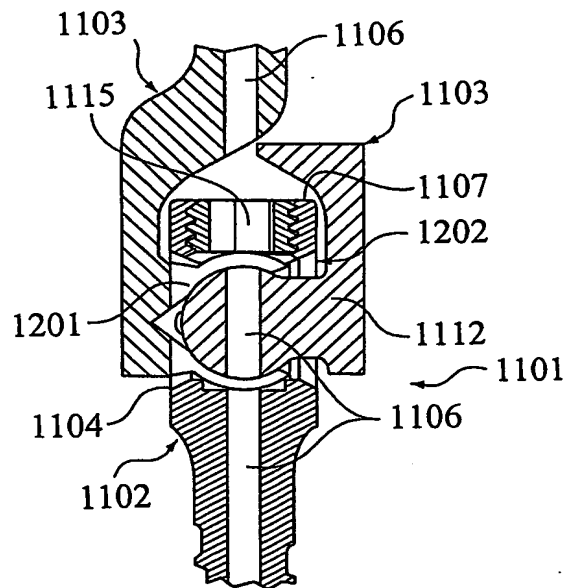


FIG. 12D

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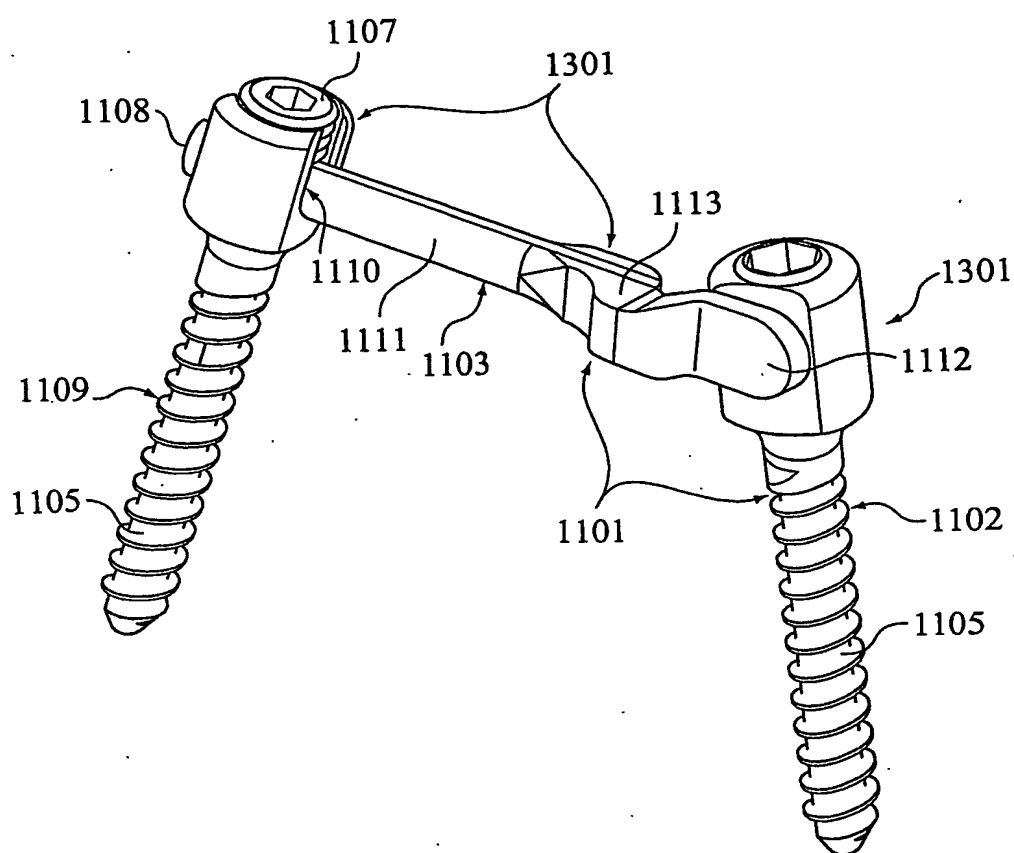


FIG. 13A

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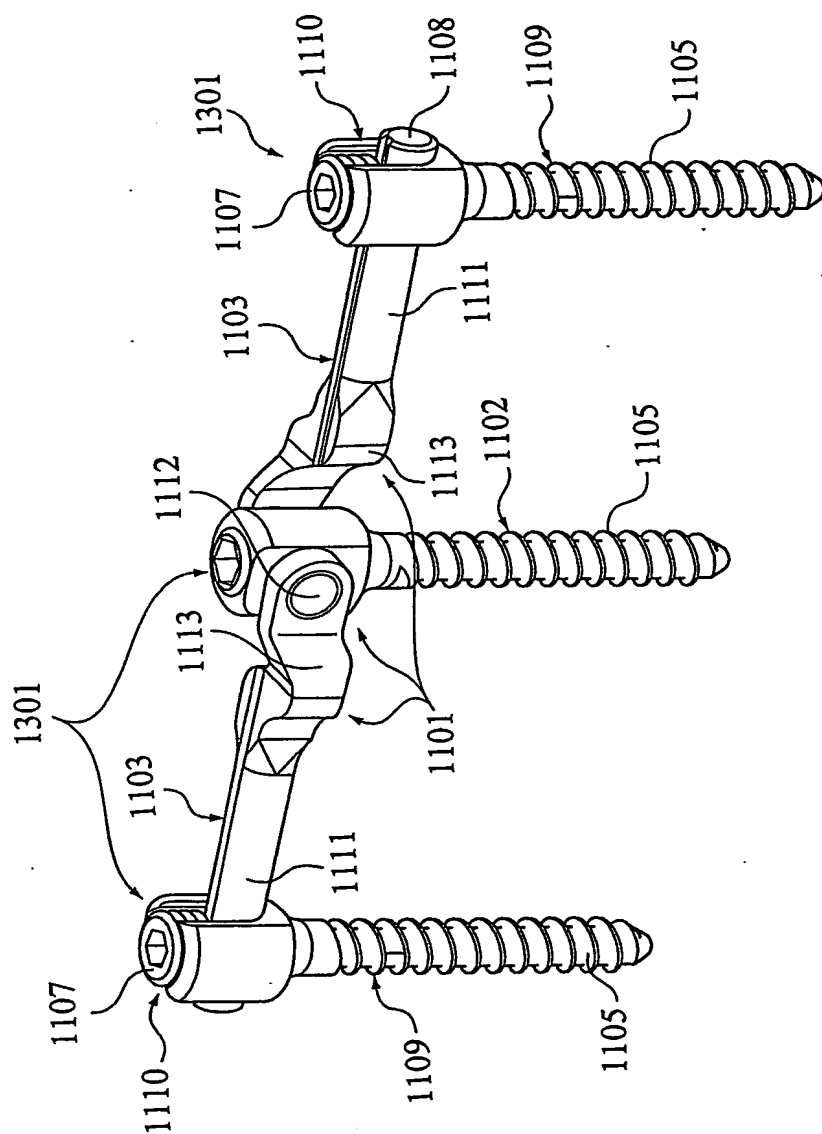


FIG. 13B

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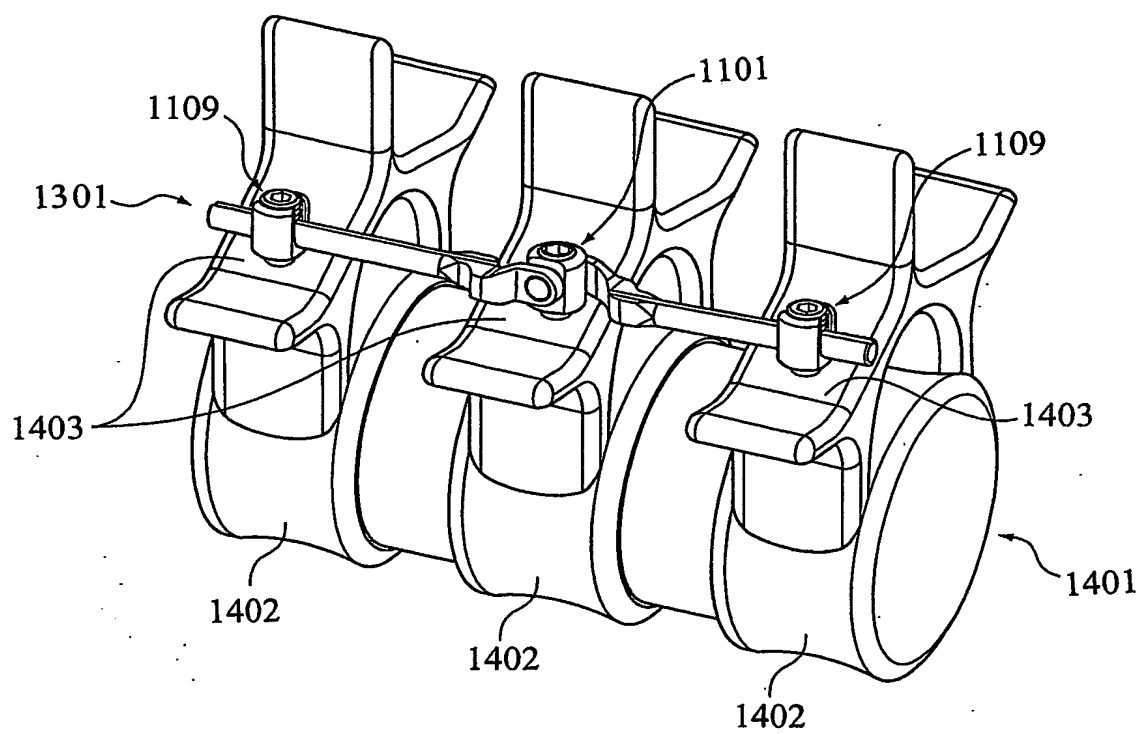


FIG. 14

# INTERNATIONAL SEARCH REPORT

Application No  
PCT/US2005/012657

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 2004/093701 A (SDGI HOLDINGS, INC; FARRIS, ROBERT, A; FOLEY, KEVIN, T; COATES, BRADLE) 4 November 2004 (2004-11-04) page 2, line 25 - page 4, line 31 figures	1, 13-18, 20, 21
X	US 5 876 403 A (SHITOTO ET AL) 2 March 1999 (1999-03-02)  column 2, line 8 - column 3, line 28 figures	1, 3, 4, 9, 10, 12-21, 23
X	US 5 649 926 A (HOWLAND ET AL) 22 July 1997 (1997-07-22) column 2, line 39 - column 6, line 15 figures  -/-	1, 9-17, 20-23



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

### \* Special categories of cited documents:

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Date of the actual completion of the international search

28 July 2005

Date of mailing of the international search report

10/08/2005

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# INTERNATIONAL SEARCH REPORT

Application No  
PCT/US2005/012657

## C-(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/105460 A1 (CRANDALL DENNIS ET AL) 5 June 2003 (2003-06-05) paragraph '0042! - paragraph '0045! paragraph '0048! - paragraph '0059! figures 21-38	1,9, 12-23
X	US 2003/032957 A1 (MCKINLEY LAURENCE M ET AL) 13 February 2003 (2003-02-13) paragraph '0030! - paragraph '0036! figures 2a,4a,4b,7	1,13-17, 20,21
A	WO 02/076315 A (FERREE, BRET, A) 3 October 2002 (2002-10-03) page 17, line 7 - line 14 page 25, line 3 - line 12 figures 3i,30A-30C	1,2,24
A	DE 94 02 695 U1 (KERNFORSCHUNGSZENTRUM KARLSRUHE GMBH, 76133 KARLSRUHE, DE) 14 April 1994 (1994-04-14) figures	1,25,40



## INTERNATIONAL SEARCH REPORT

application No.  
PCT/US2005/012657

### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **41-43**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery**
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

on patent family members

Application No

PCT/US2005/012657

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2004093701	A	04-11-2004	US 2004210216 A1 WO 2004093701 A2	21-10-2004 04-11-2004
US 5876403	A	02-03-1999	JP 2871620 B2 JP 10080430 A	17-03-1999 31-03-1998
US 5649926	A	22-07-1997	US 5545166 A AU 3096295 A WO 9602200 A1	13-08-1996 16-02-1996 01-02-1996
US 2003105460	A1	05-06-2003	US 2002082599 A1 US 6309391 B1 AT 265188 T AU 4167101 A CA 2403051 A1 DE 60103031 D1 DE 60103031 T2 EP 1263339 A2 ES 2219513 T3 JP 2003526443 T WO 0167973 A2	27-06-2002 30-10-2001 15-05-2004 24-09-2001 20-09-2001 03-06-2004 27-01-2005 11-12-2002 01-12-2004 09-09-2003 20-09-2001
US 2003032957	A1	13-02-2003	NONE	
WO 02076315	A	03-10-2002	EP 1381323 A1 JP 2004535217 T WO 02076315 A1 US 2002138077 A1 US 2004260287 A1	21-01-2004 25-11-2004 03-10-2002 26-09-2002 23-12-2004
DE 9402695	U1	14-04-1994	NONE	

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